US009220870B2

(12) **United States Patent**
Hyman et al.

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(45) **Date of Patent: Dec. 29, 2015**

(54) **CATHETER SECUREMENT DEVICES**

(71) Applicant: **INSIGHTRA MEDICAL INCORPORATED**, Irvine, CA (US)

(72) Inventors: **Daniel Hyman**, Irvine, CA (US); **Wayne A. Noda**, Irvine, CA (US); **Stephen G. Bell**, Irvine, CA (US)

(73) Assignee: **Insightra Medical Incorporated**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 58 days.

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(86) PCT No.: **PCT/US2013/022070**

§ 371 (c)(1),
(2) Date: **Jan. 16, 2014**

(87) PCT Pub. No.: **WO2013/109835**

PCT Pub. Date: **Jul. 25, 2013**

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Related U.S. Application Data

(60) Provisional application No. 61/588,515, filed on Jan. 19, 2012, provisional application No. 61/652,589, filed on May 29, 2012.

(51) **Int. Cl.**
A61M 5/32 (2006.01)
A61M 25/02 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 25/02*** (2013.01); *A61M 2025/024* (2013.01); *A61M 2025/026* (2013.01); *A61M 2025/028* (2013.01); *A61M 2025/0253* (2013.01)

(58) **Field of Classification Search**
CPC A61M 2025/024; A61M 2025/0246; A61M 2025/0266; A61M 25/02; A61M 2025/0253; A61M 2025/026; A61M 2025/028
See application file for complete search history.

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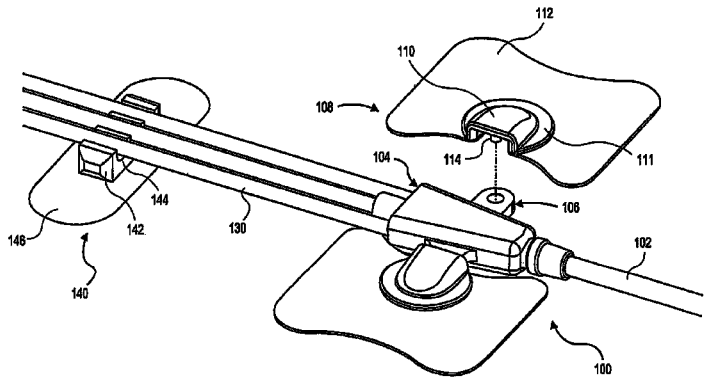
Primary Examiner — Rebecca E Eisenberg
(74) *Attorney, Agent, or Firm* — John L. Rogitz

(57) **ABSTRACT**

Described herein are catheter securement devices that can be used to secure catheters, catheter hubs and other medical devices to the body of a patient. The catheter securement devices can include an adhesive pad and engagement tabs with a slide locking feature. Adaptors can be used to provide suture tabs to catheters that lack suture tabs.

19 Claims, 33 Drawing Sheets



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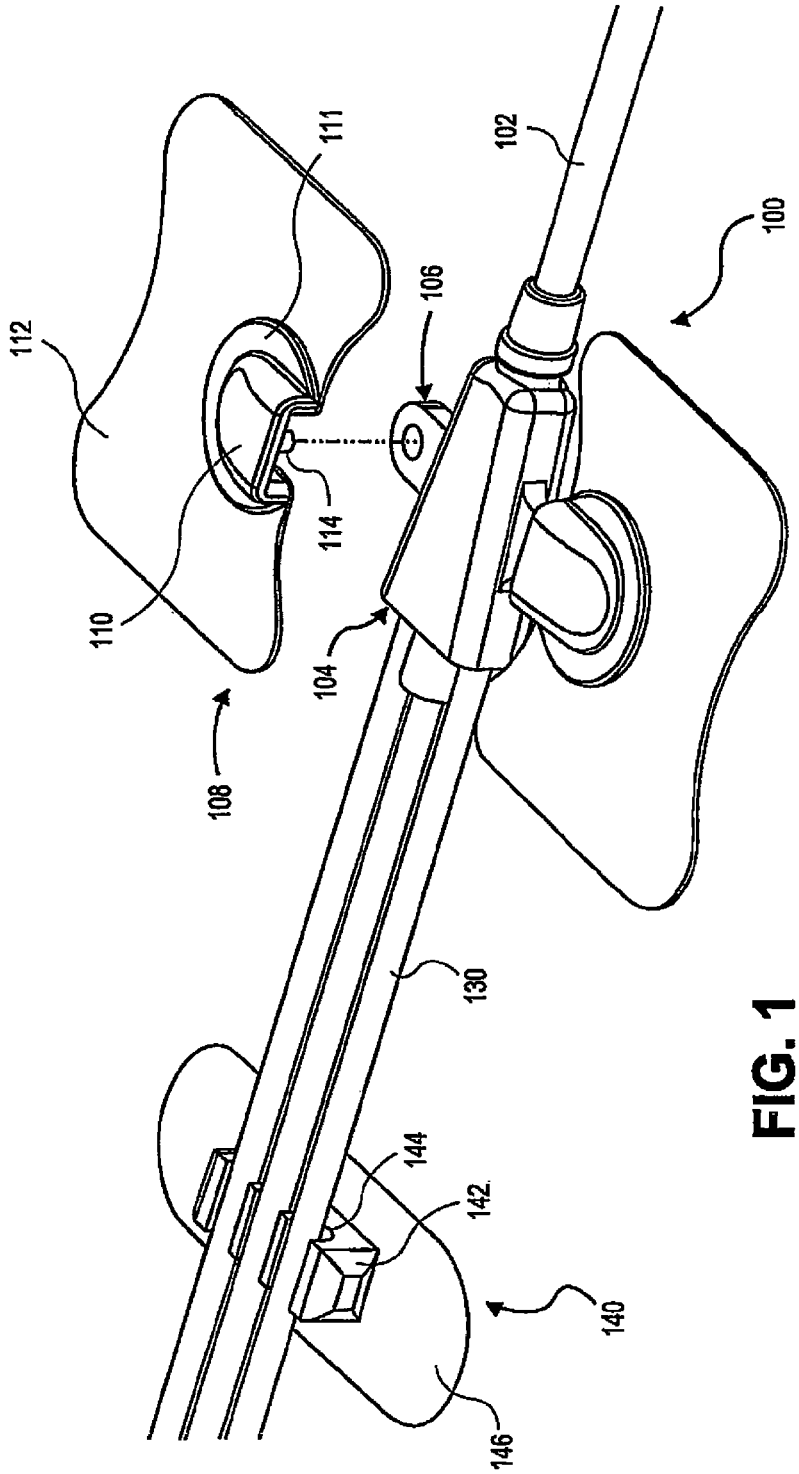


FIG. 1

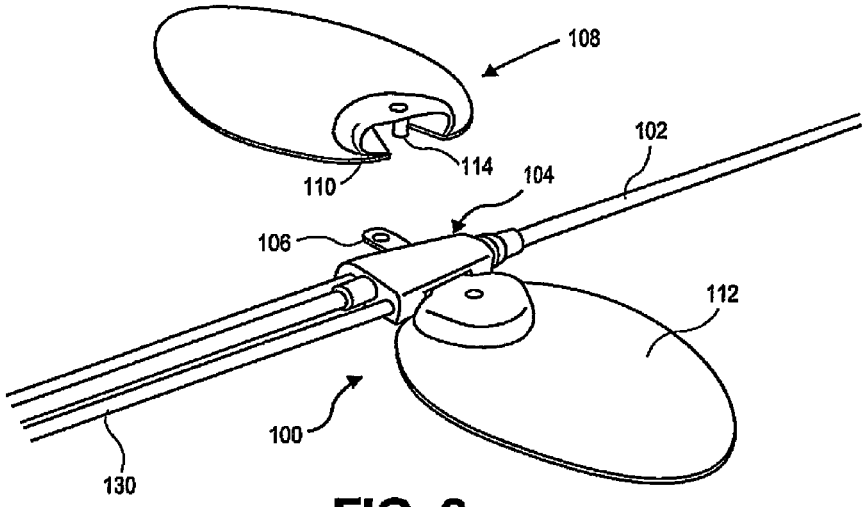


FIG. 2

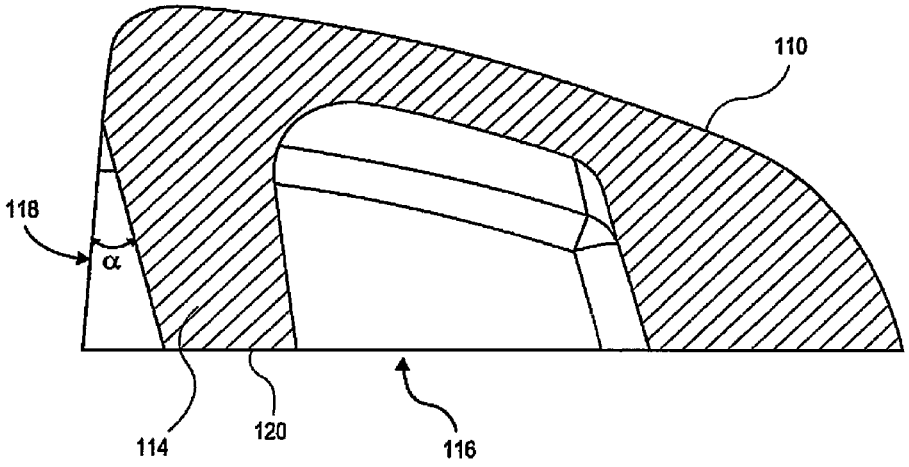


FIG. 3

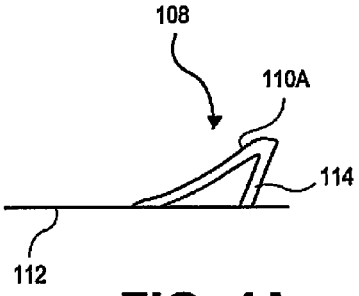


FIG. 4A

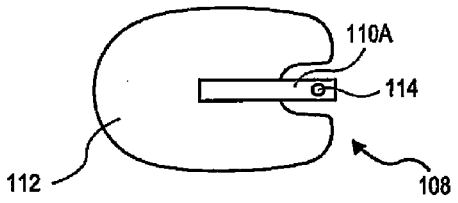


FIG. 4B

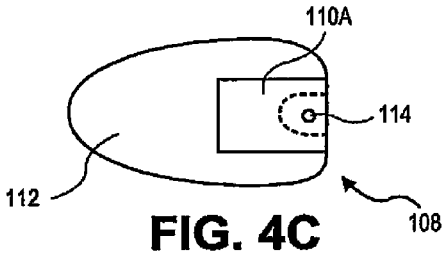


FIG. 4C

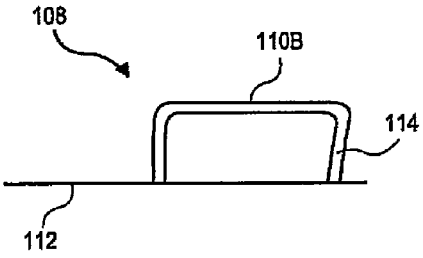


FIG. 5A

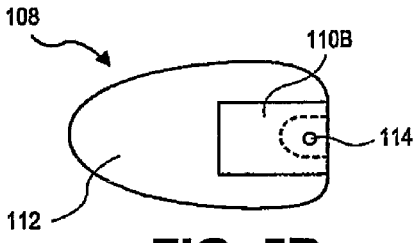
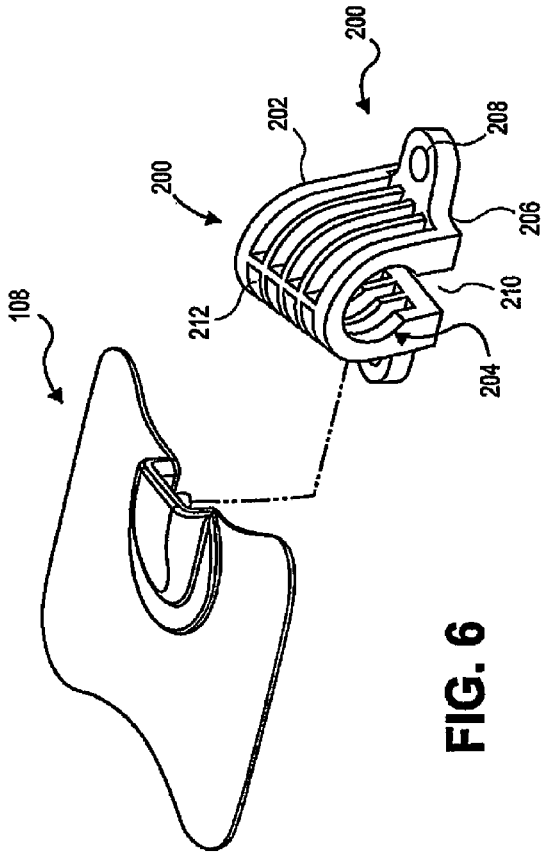


FIG. 5B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202
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206
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212
210
204

FIG. 6

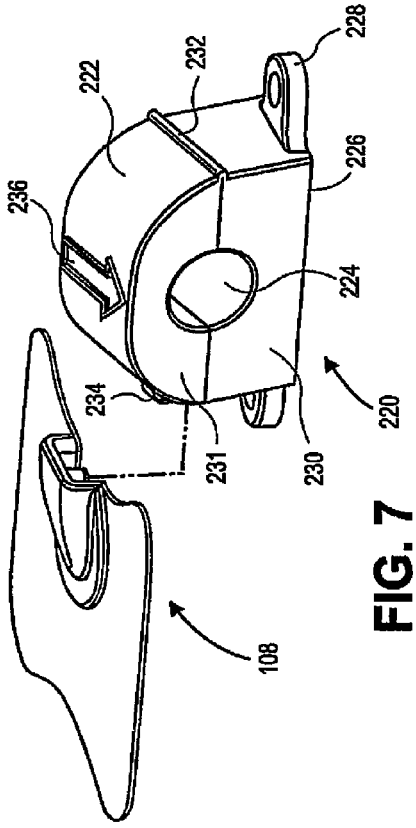
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FIG. 7

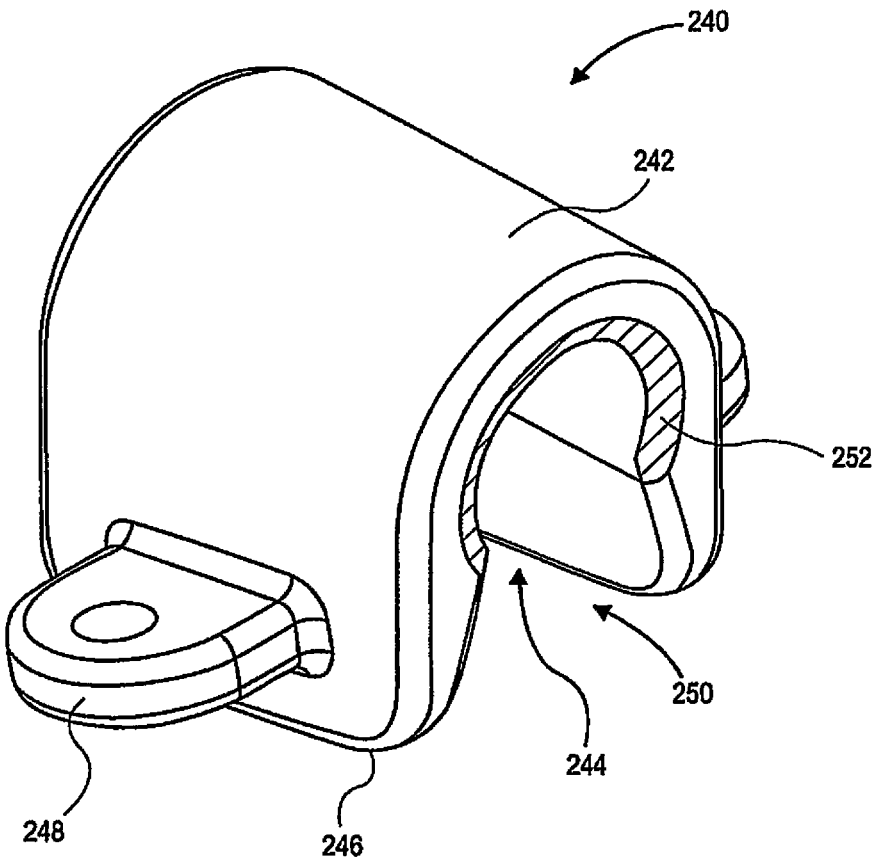


FIG. 8

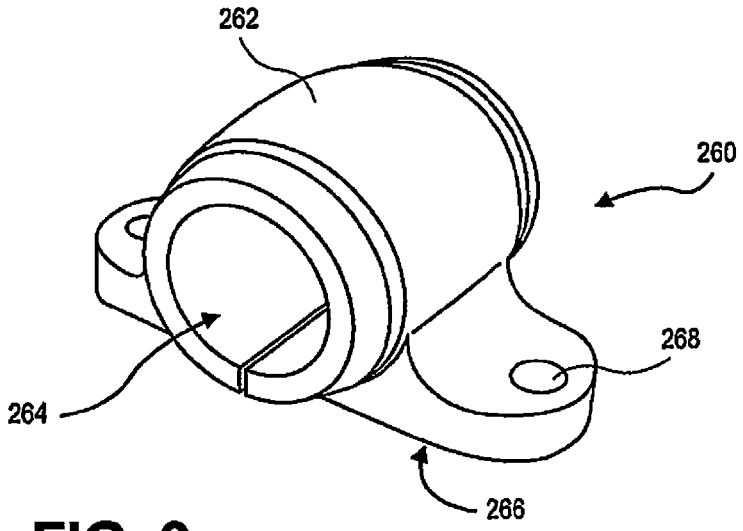


FIG. 9

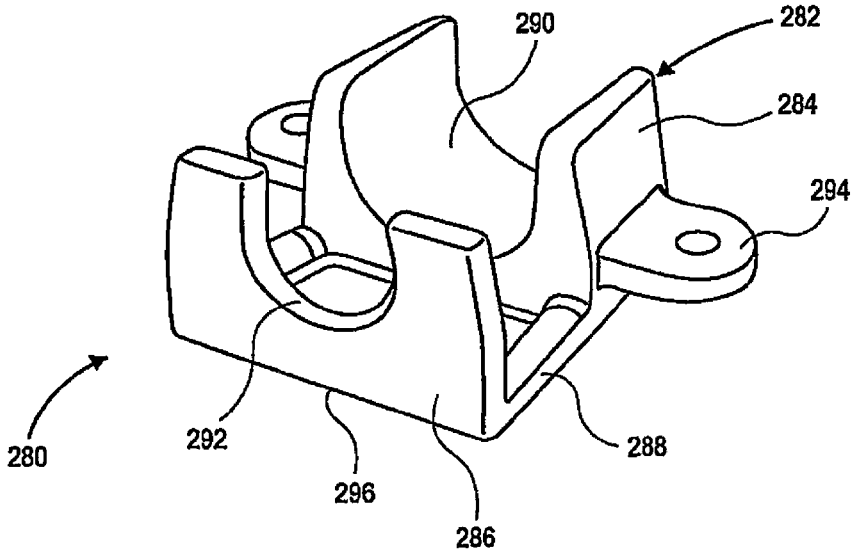


FIG. 10

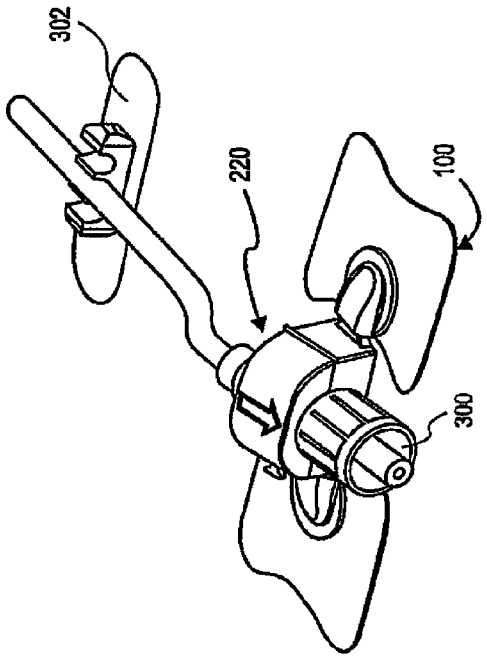


FIG. 11C

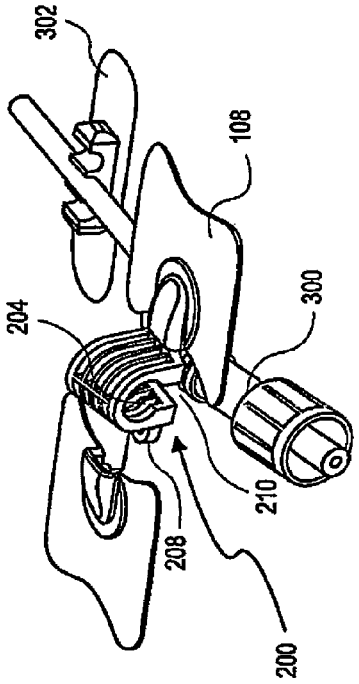


FIG. 11A

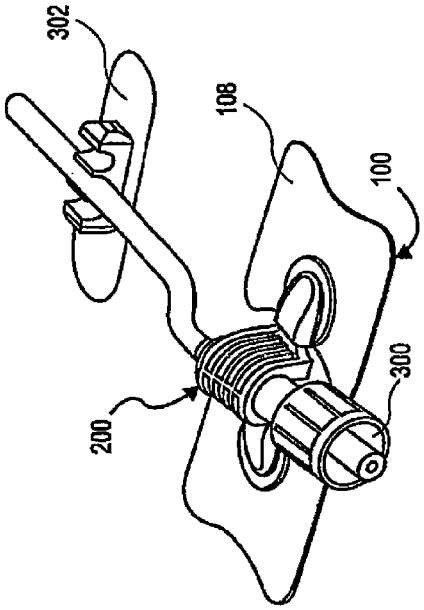


FIG. 11B

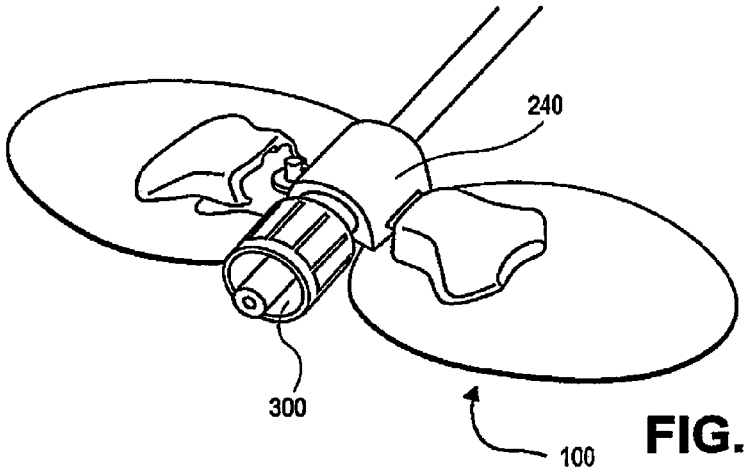


FIG. 11D

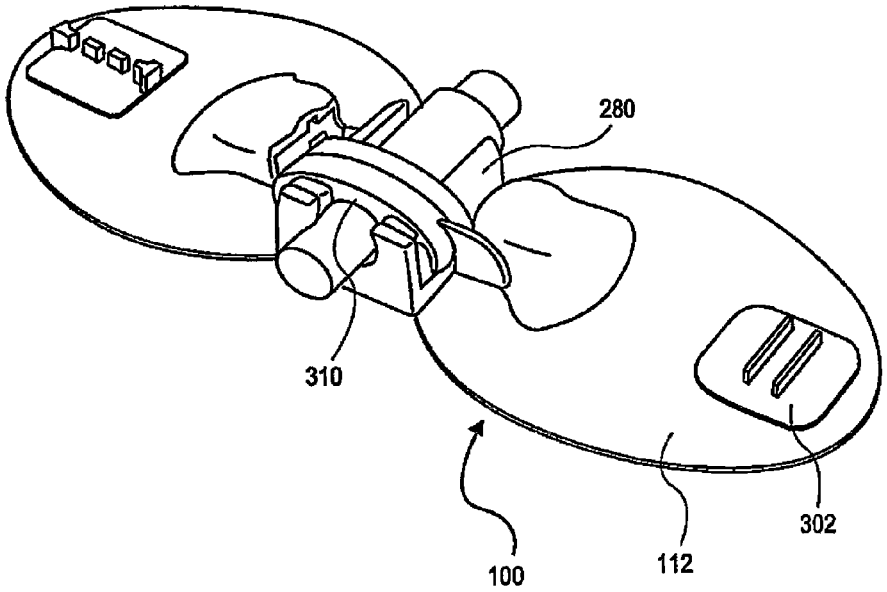
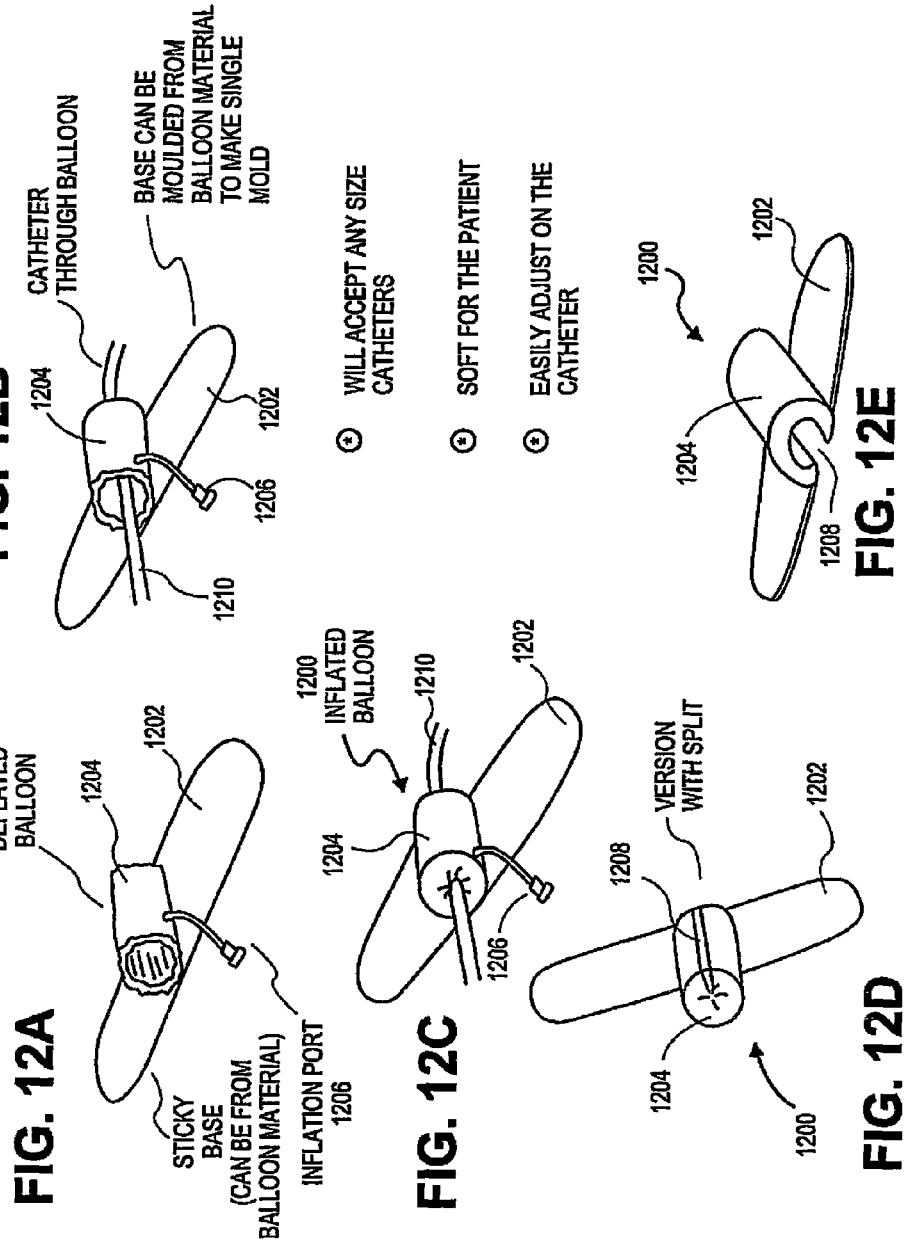


FIG. 11E

BALLOON CATHETER SECUREMENT : DISCLOSURE



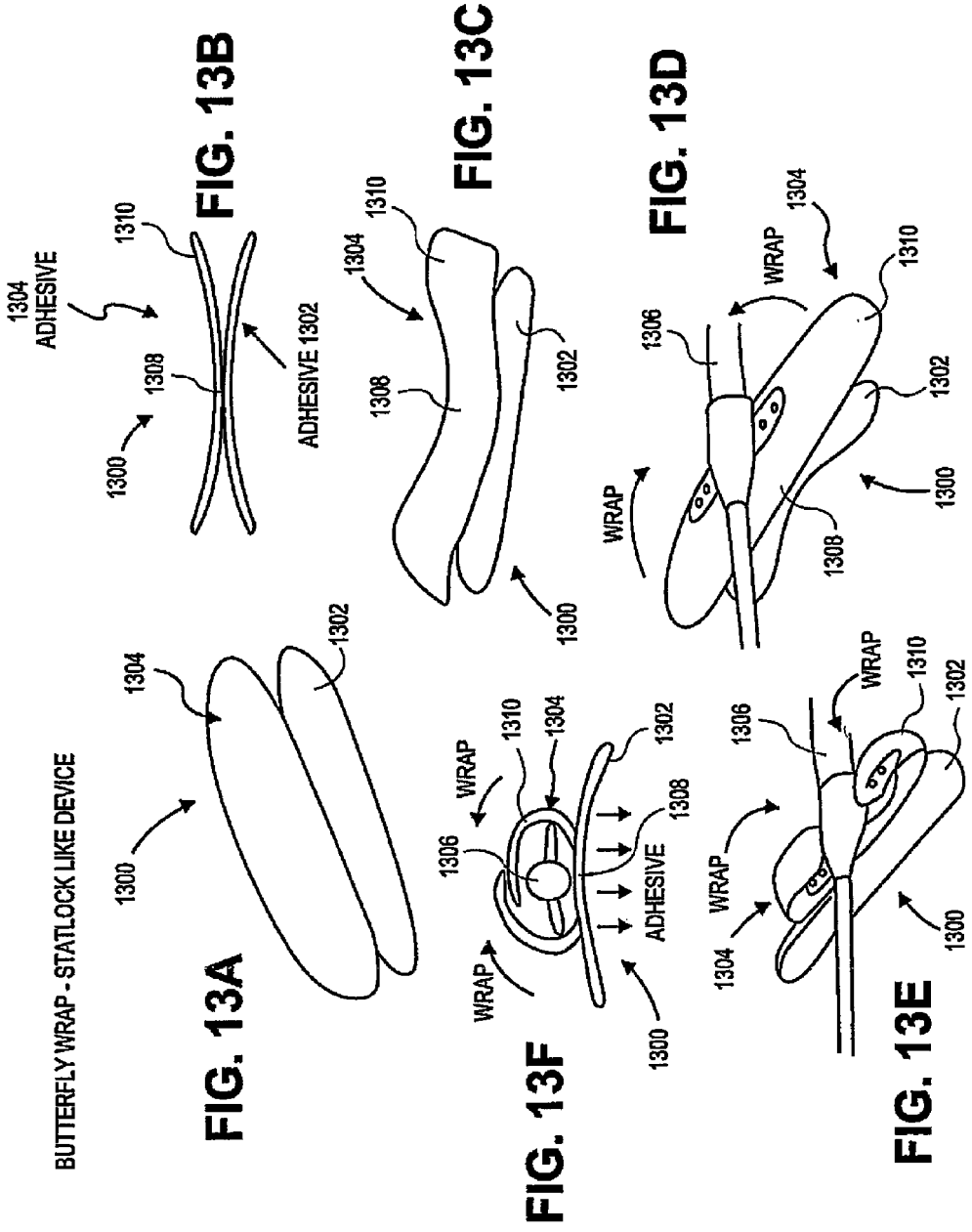


FIG. 13A

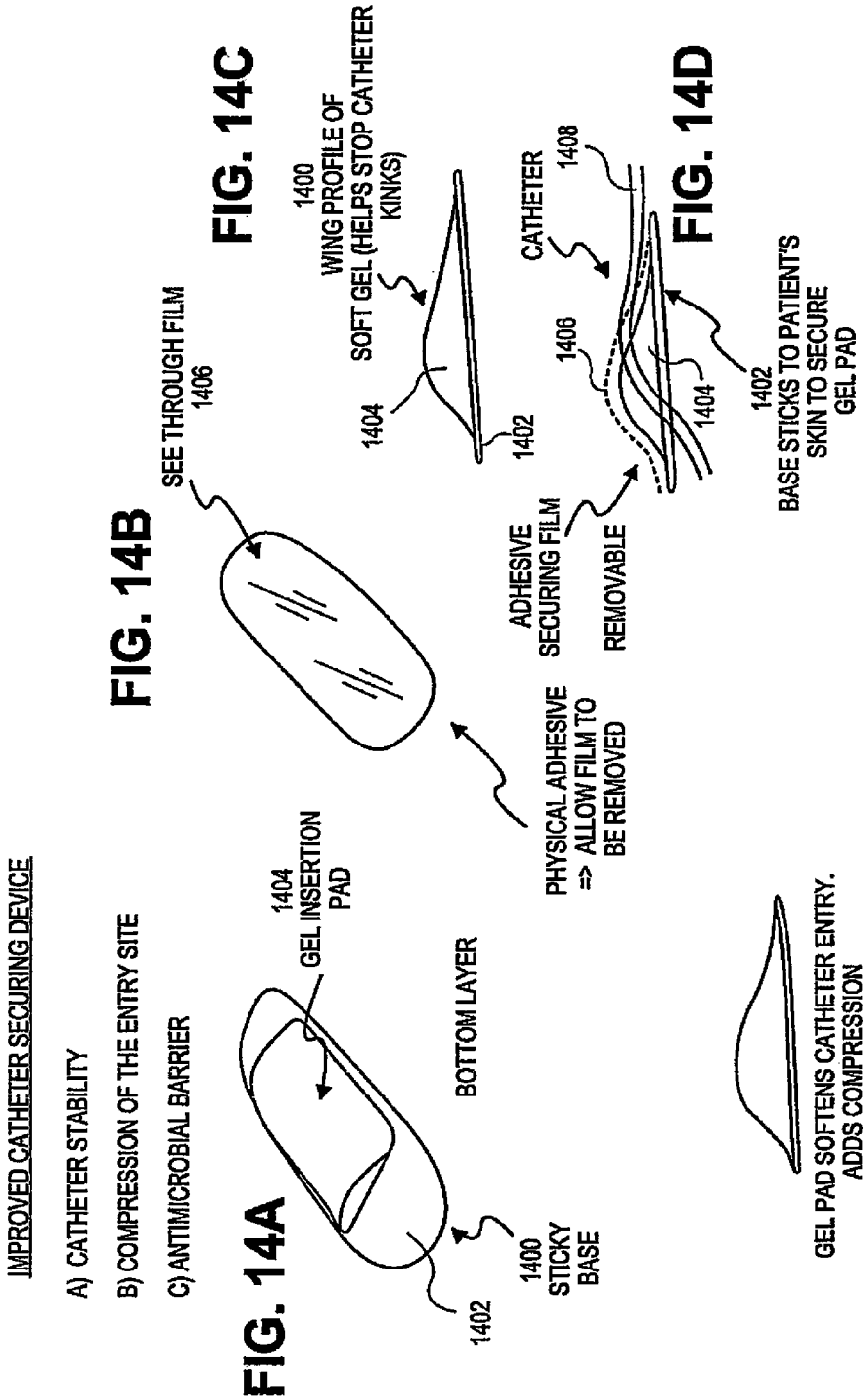
FIG. 13B

FIG. 13C

FIG. 13D

FIG. 13E

FIG. 13F


IMPROVED CATHETER SECURING DEVICE
A) CATHETER STABILITY
B) COMPRESSION OF THE ENTRY SITE
C) ANTIMICROBIAL BARRIER
FIG. 14A
1404
GEL INSERTION PAD
BOTTOM LAYER
1402
1400
STICKY BASE
FIG. 14B
SEE THROUGH FILM
1406
PHYSICAL ADHESIVE
=> ALLOW FILM TO BE REMOVED
FIG. 14C
1400
WING PROFILE OF
SOFT GEL (HELPS STOP CATHETER KINKS)
1404
1402
ADHESIVE SECURING FILM
REMOVABLE
CATHETER
1408
1406
1404
1402
BASE STICKS TO PATIENT'S SKIN TO SECURE GEL PAD
FIG. 14D
GEL PAD SOFTENS CATHETER ENTRY.
ADDS COMPRESSION
CAN BE IMPREGNATED WITH
ANTIBIOTICS OR OTHER
ANTIMICROBIALS

CATHETER SECUREMENT DEVICES

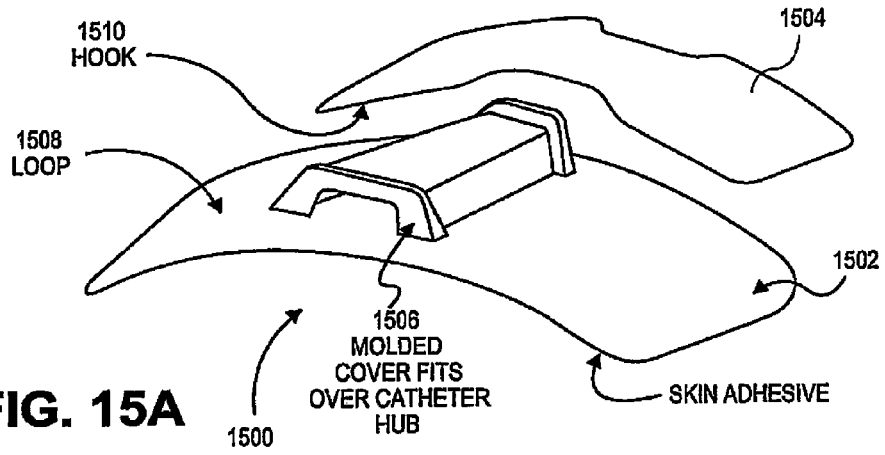


FIG. 15A

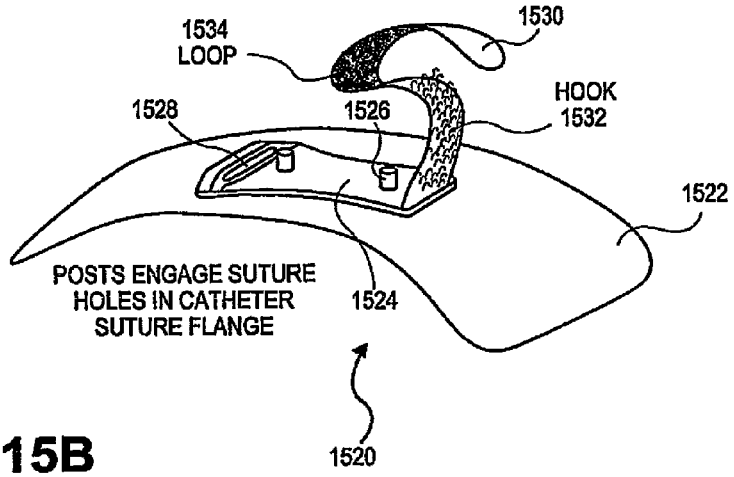


FIG. 15B

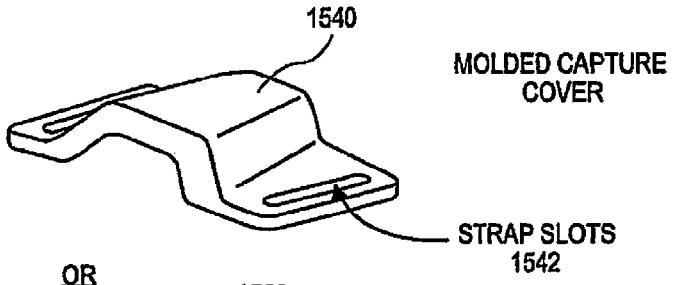


FIG. 15C

OR

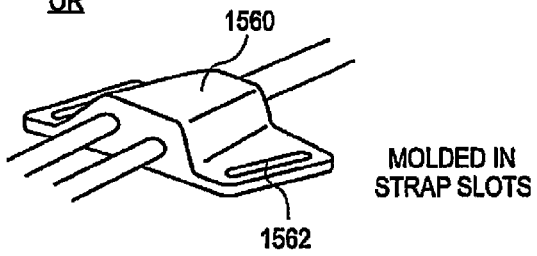


FIG. 15D

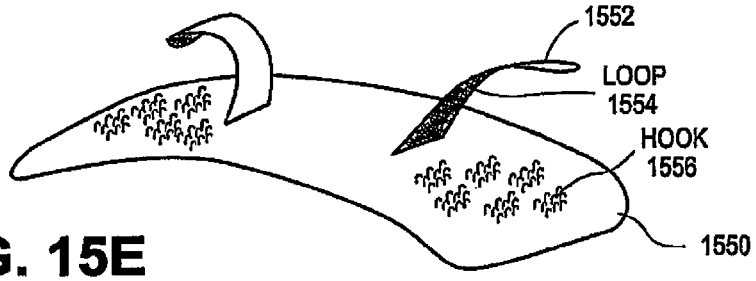


FIG. 15E

OR

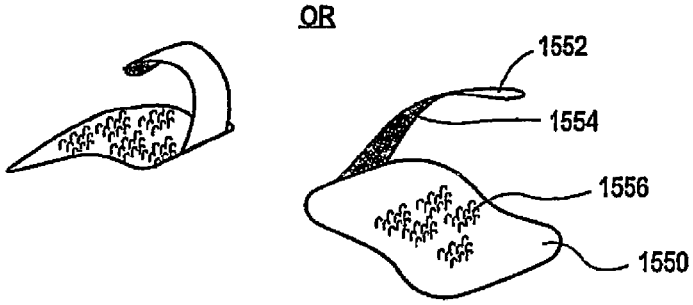


FIG. 15F

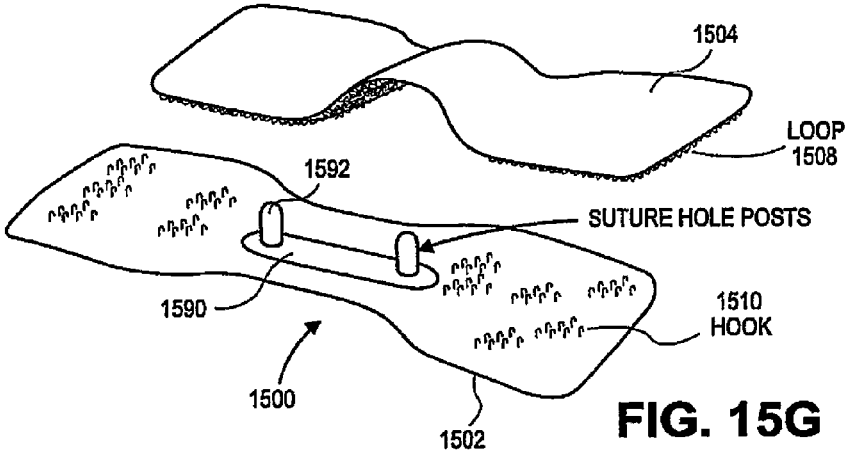


FIG. 15G

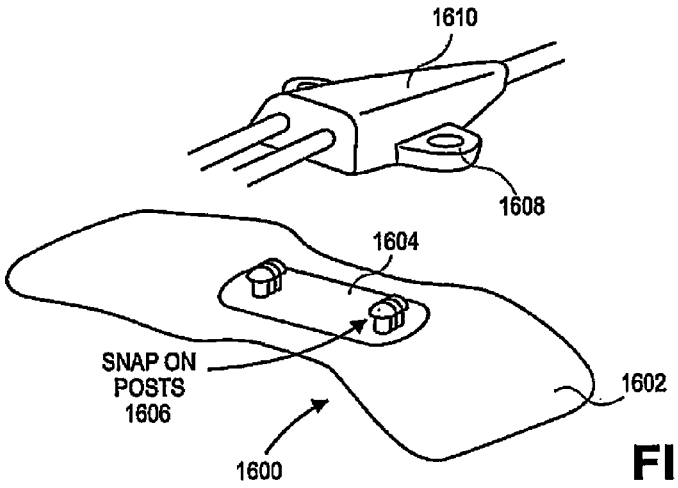


FIG. 16

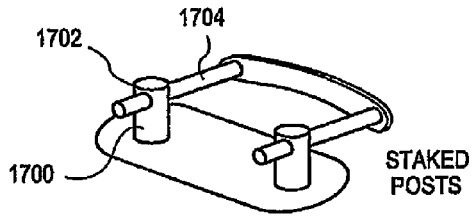


FIG. 17

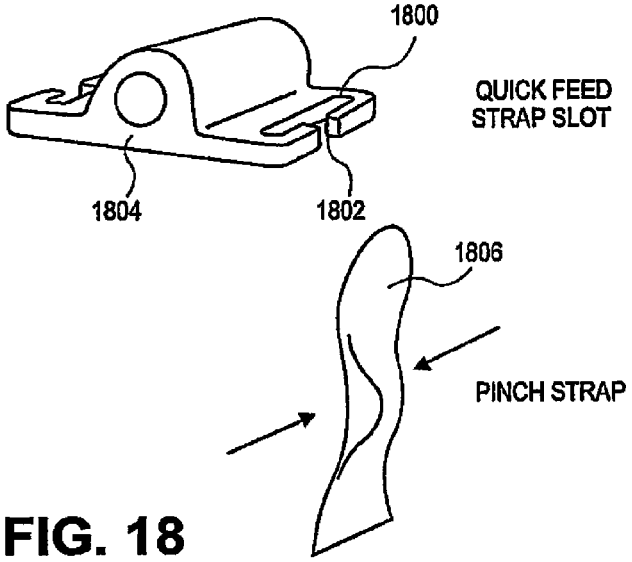
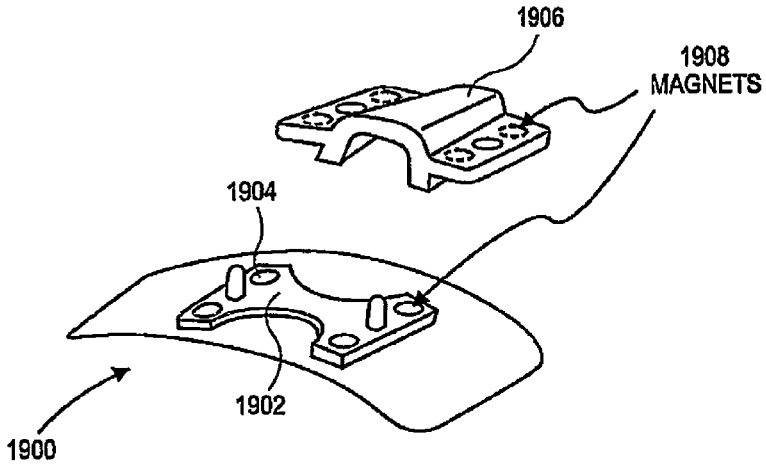

1800
QUICK FEED
STRAP SLOT
1804
1802
1806
PINCH STRAP

FIG. 18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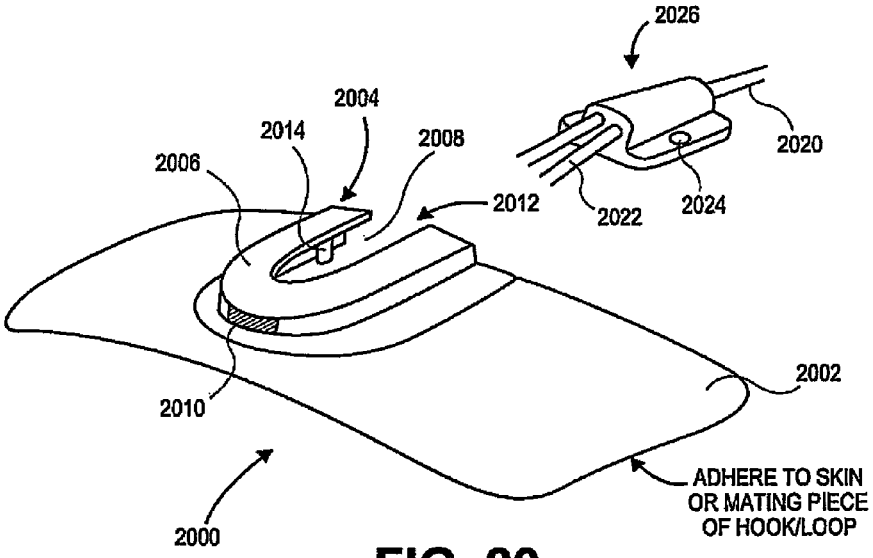
1908
MAGNETS
1904
1902
1900

FIG. 19


2026
2004
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2008
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2022
2024
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ADHERE TO SKIN
OR MATING PIECE
OF HOOK/LOOP
2000

FIG. 20

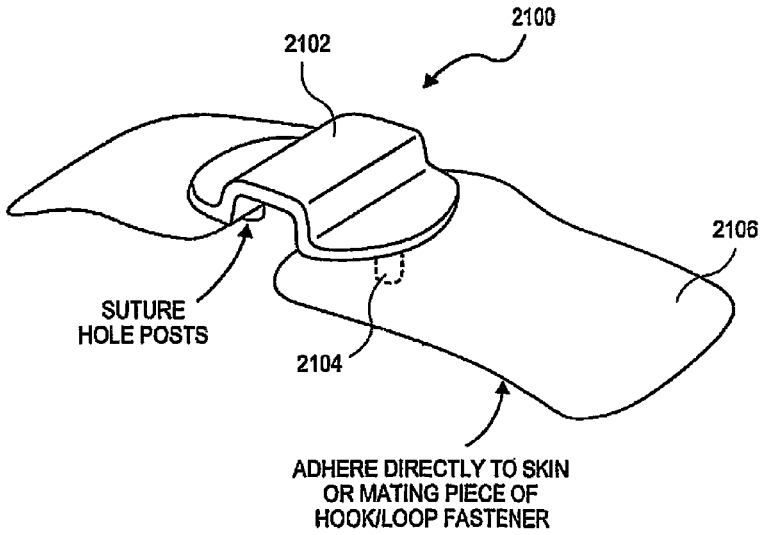

2100
2102
2106
SUTURE
HOLE POSTS
2104
ADHERE DIRECTLY TO SKIN
OR MATING PIECE OF
HOOK/LOOP FASTENER

FIG. 21

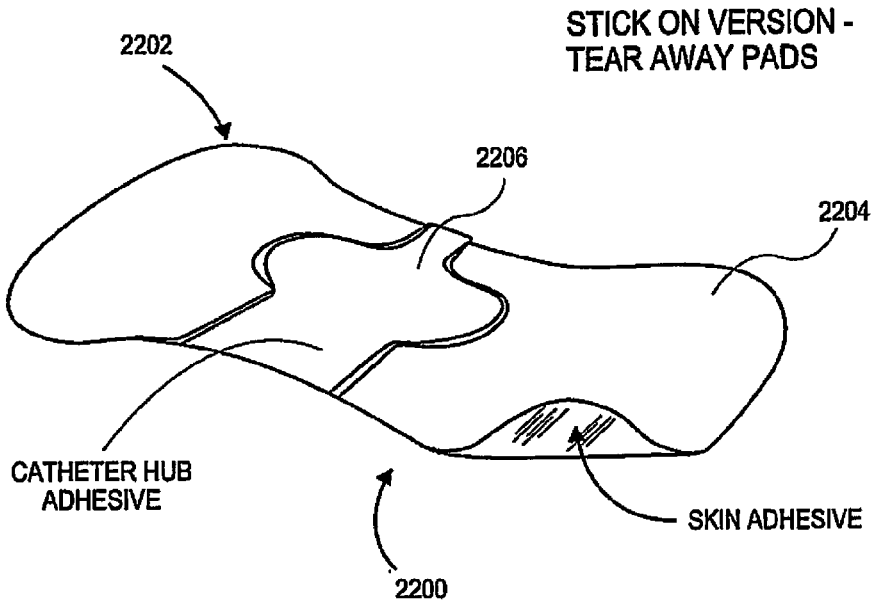

STICK ON VERSION -
TEAR AWAY PADS
2202
2206
2204
CATHETER HUB
ADHESIVE
SKIN ADHESIVE
2200

FIG. 22A

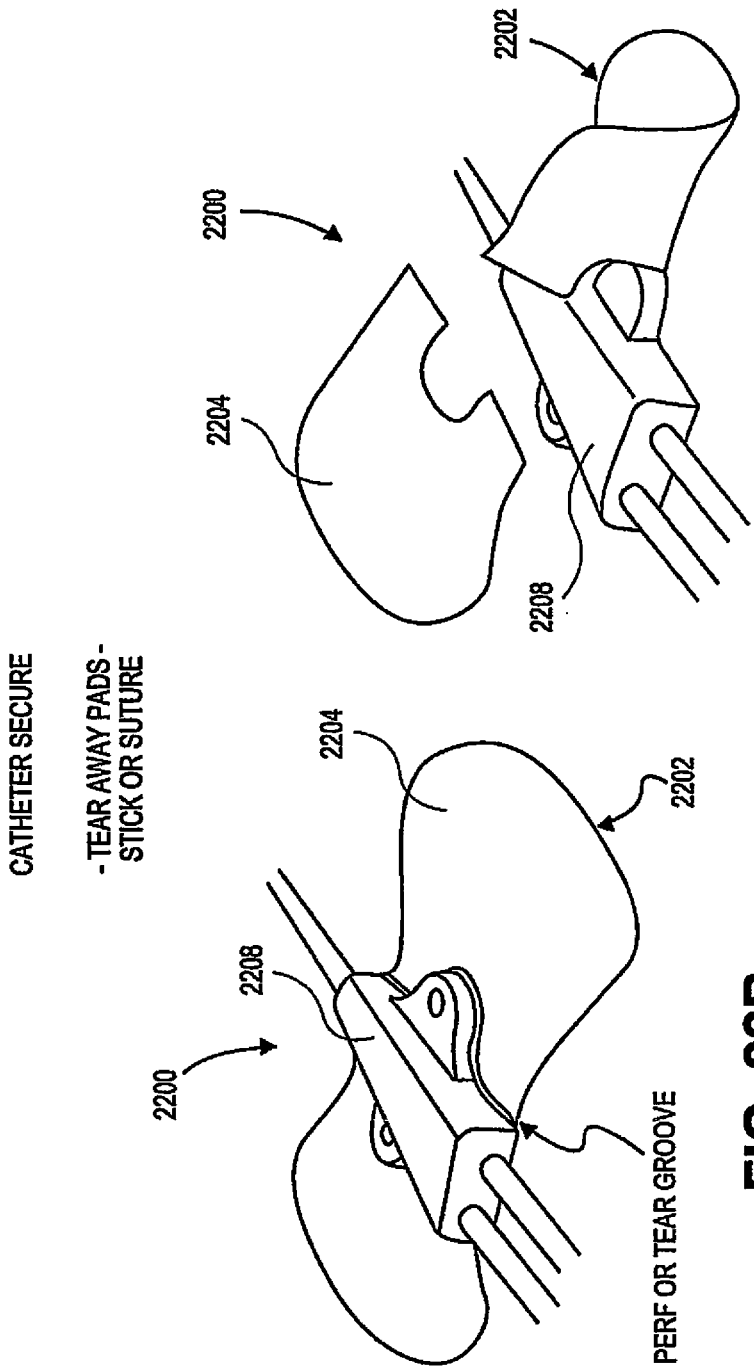


FIG. 22B

FIG. 22C

CATHETER SECUREMENT DEVICE
STRAP AND BUCKLE OVER NESTED HUB

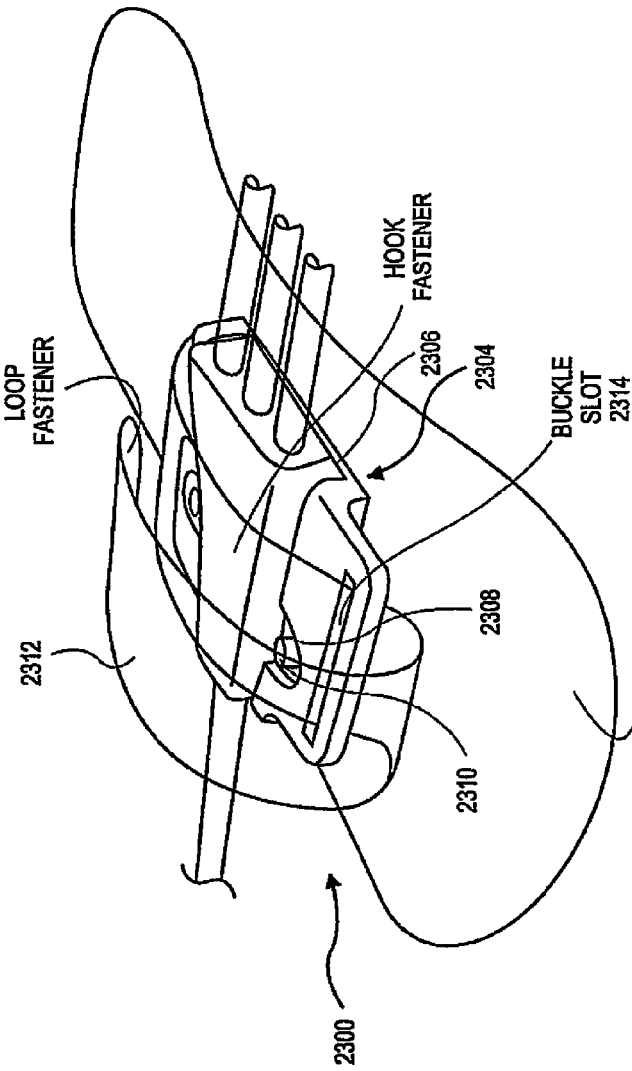


FIG. 23

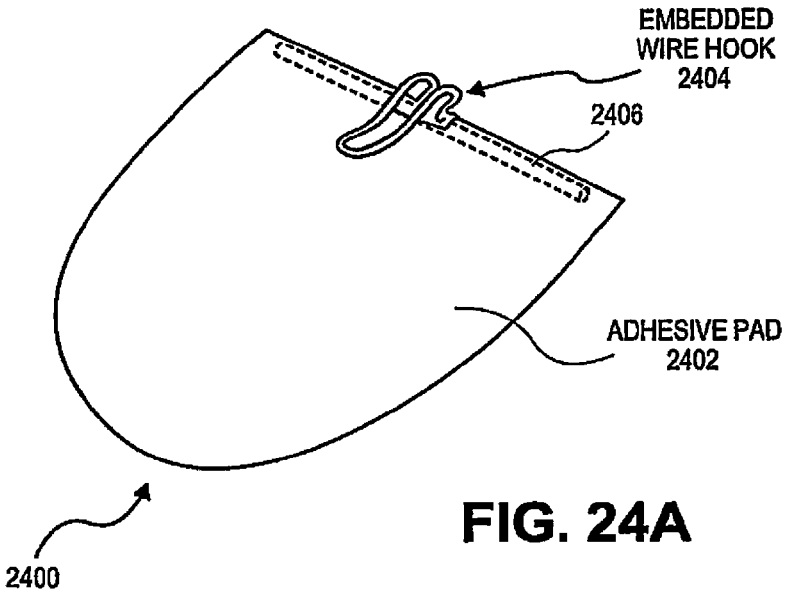


FIG. 24A

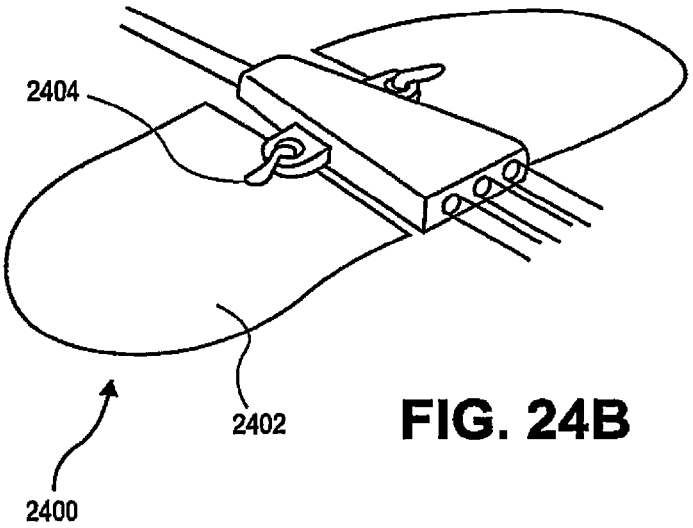


FIG. 24B

Vacuum formed Blister pack with adhesive overlay sticker with integrated tube management.

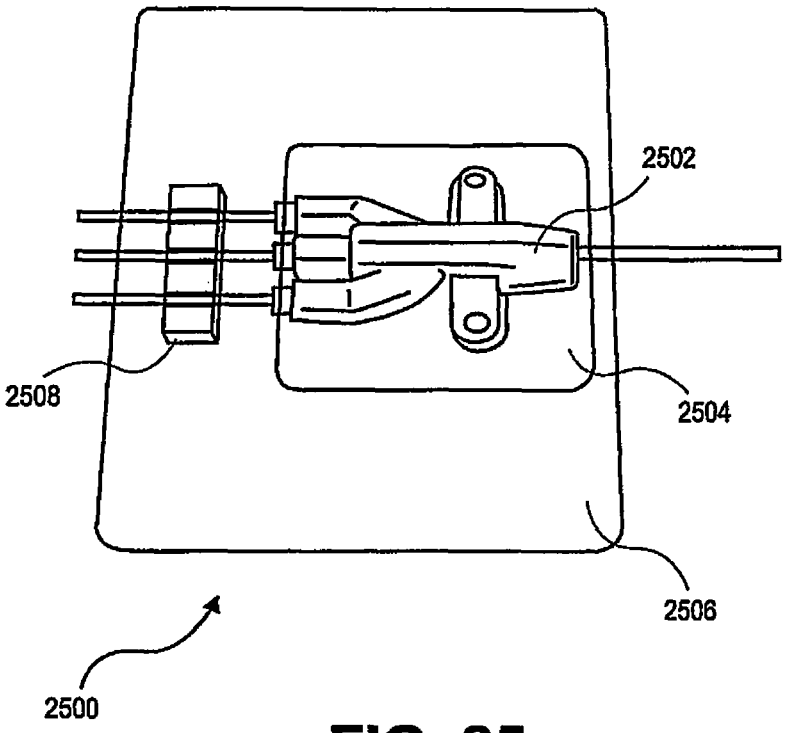


FIG. 25

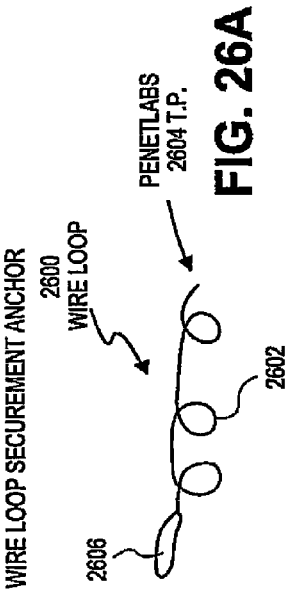


FIG. 26A

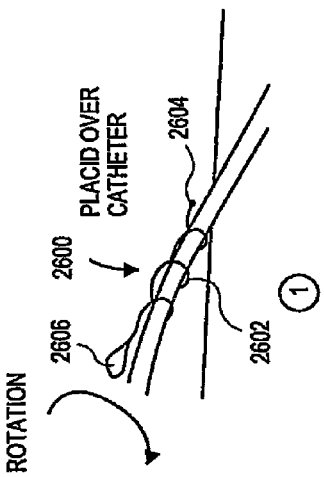


FIG. 26B

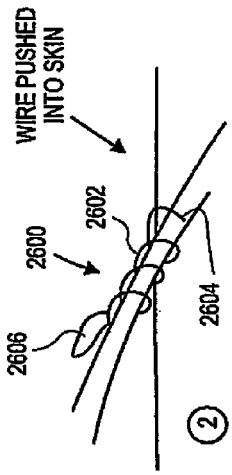


FIG. 26C

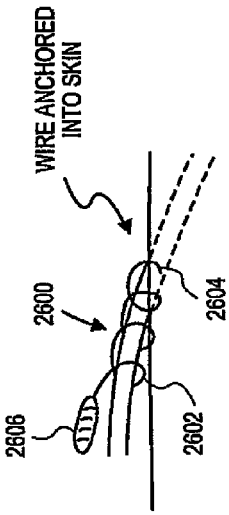


FIG. 26D

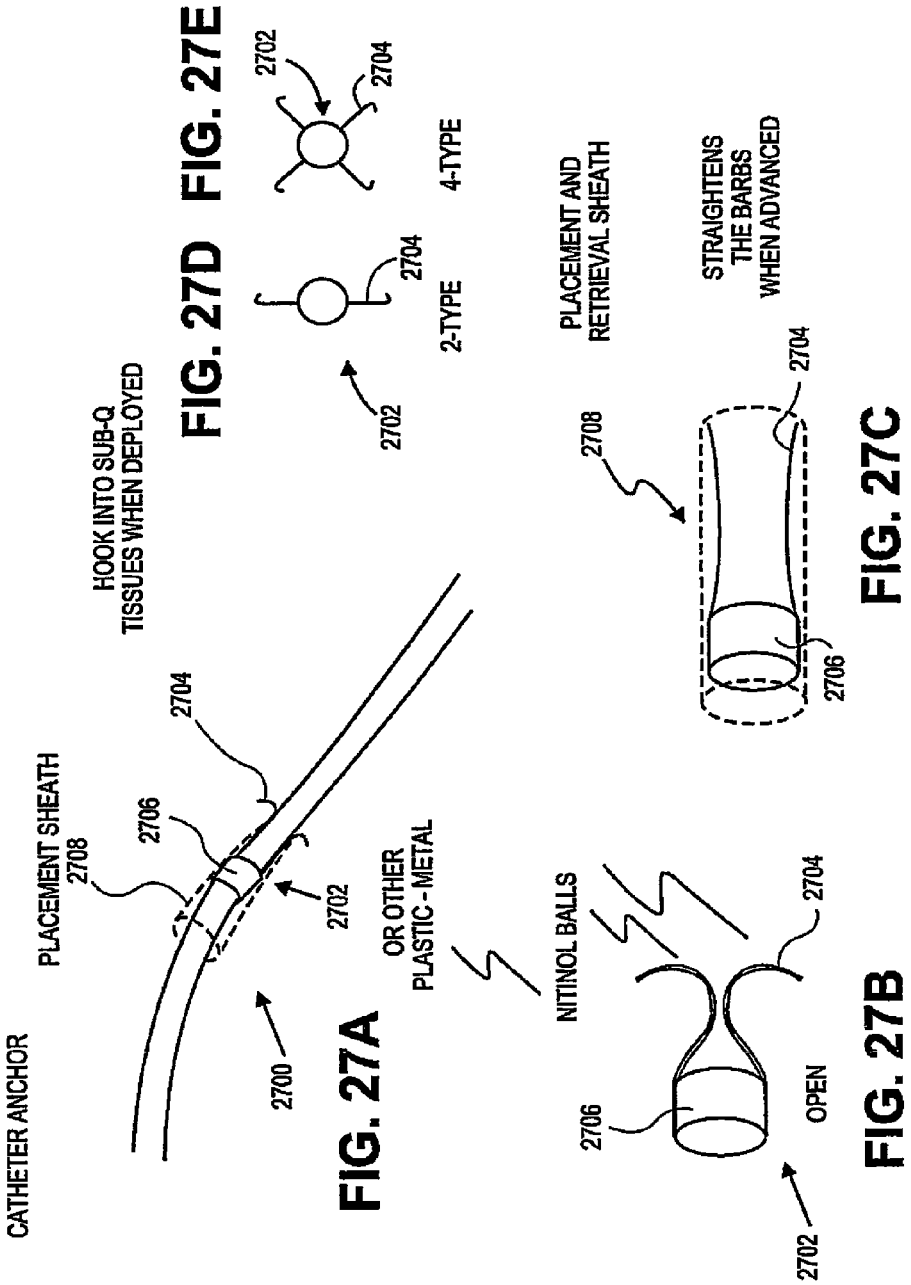


FIG. 27A

FIG. 27B

FIG. 27C

FIG. 27D

FIG. 27E

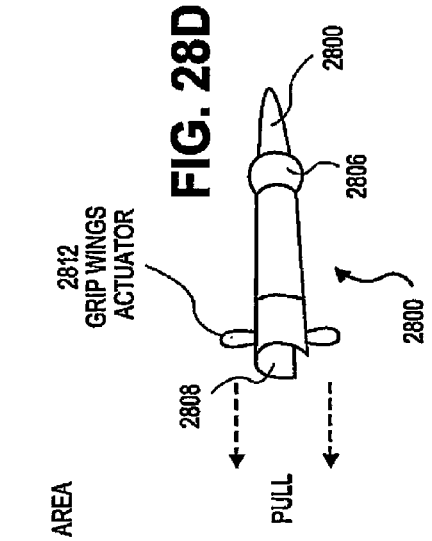


FIG. 28D

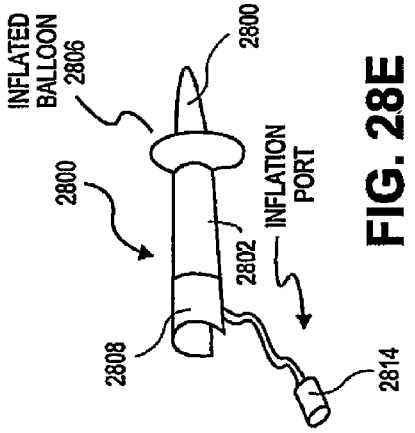


FIG. 28E

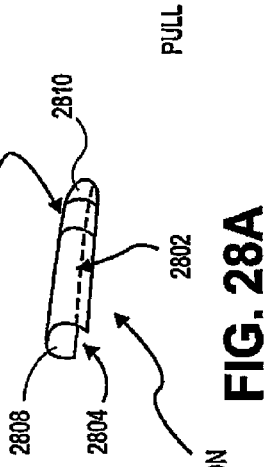


FIG. 28A

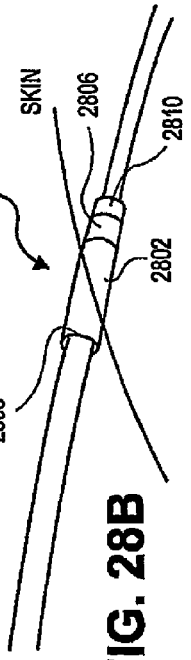


FIG. 28B

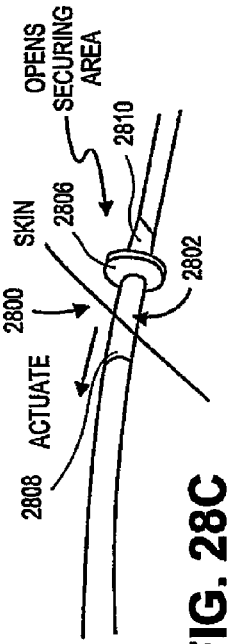


FIG. 28C

CATHETER SECURING DEVICE
FOR OVER THE CATHETER
SECUREMENT

FIG. 29A

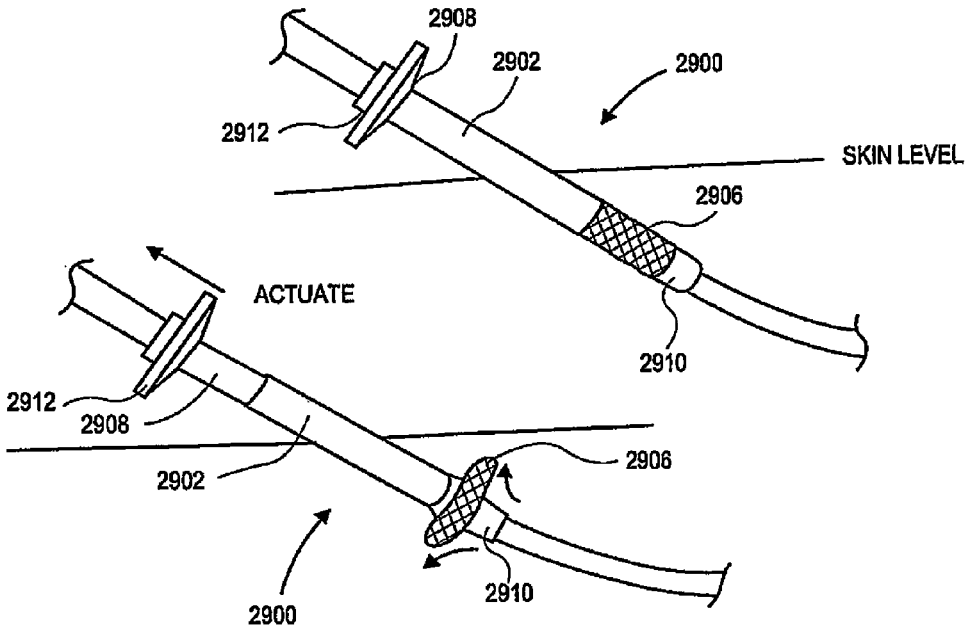


FIG. 29B

SUBCUTANEOUS EXPANDING ANCHOR

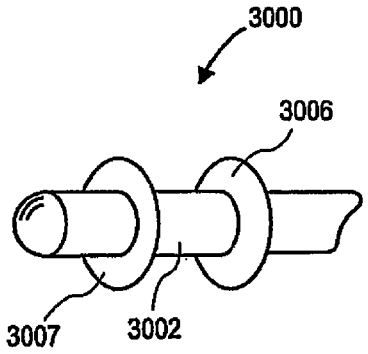


FIG. 30A

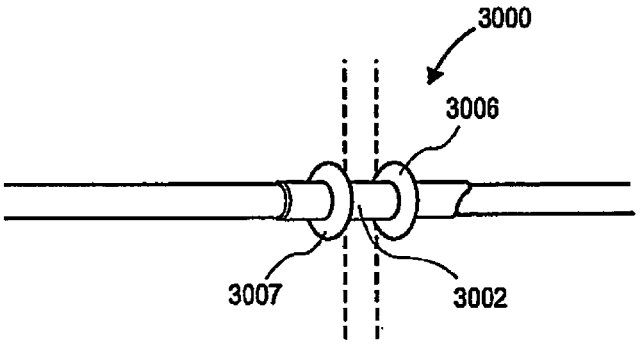


FIG. 30B

DOUBLE LOCKING CATHETER GRIP.

TO STOP IN AND OUT MOVEMENT.

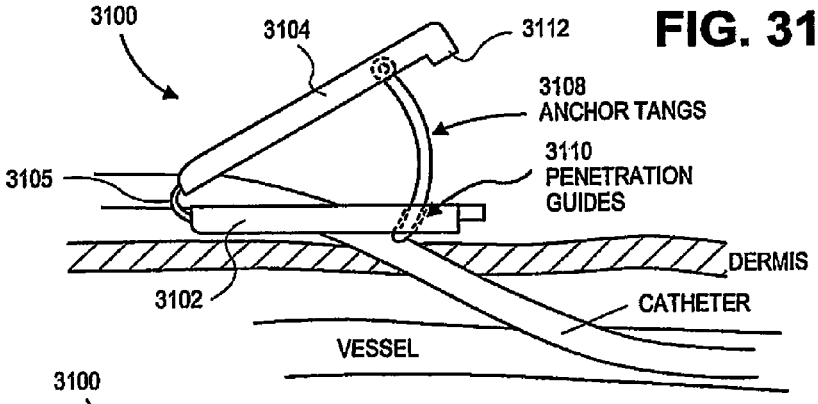


FIG. 31A

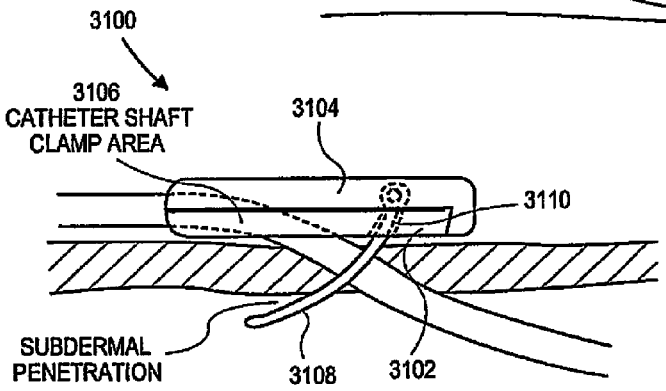


FIG. 31B

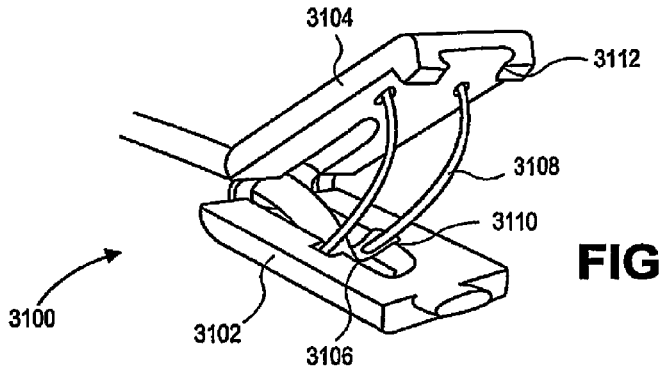


FIG. 31C

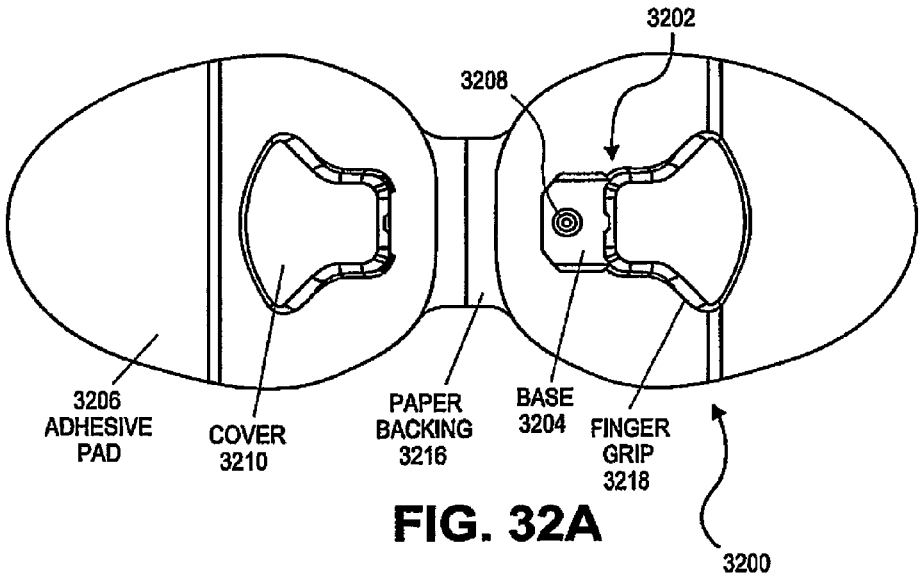


FIG. 32A

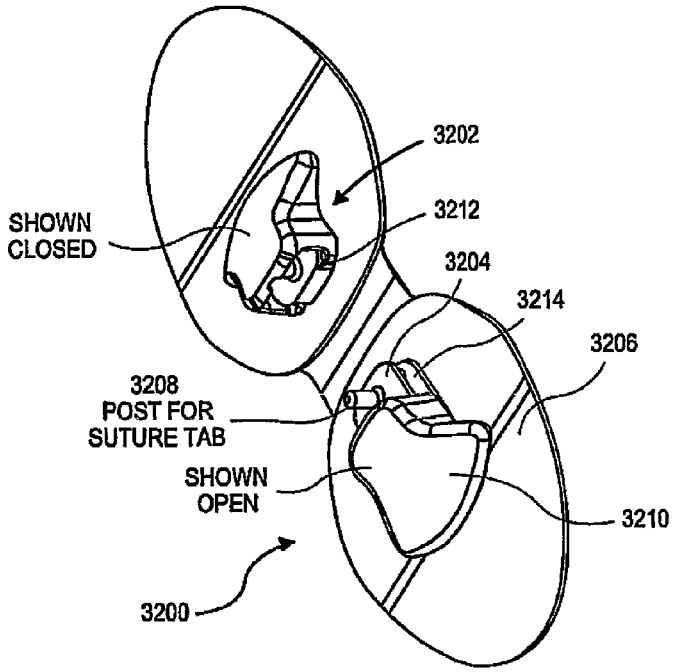
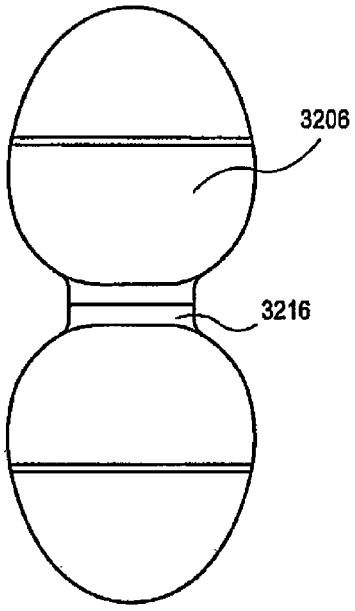
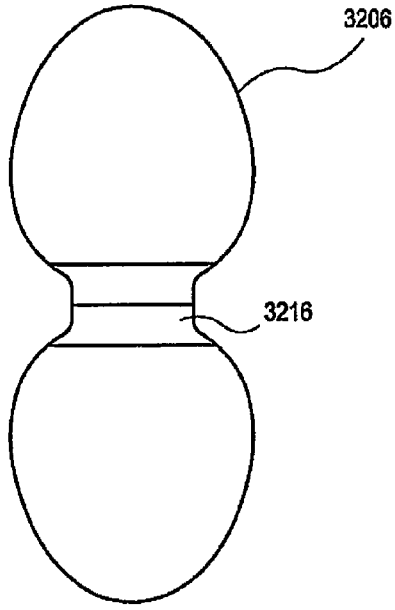


FIG. 32B



TOP VIEW

FIG. 32C



BOTTOM VIEW

FIG. 32D

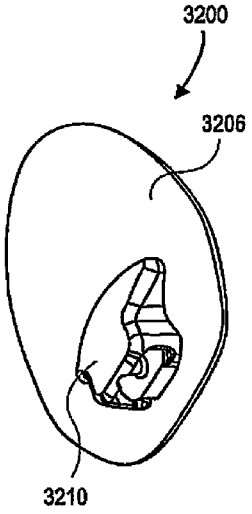
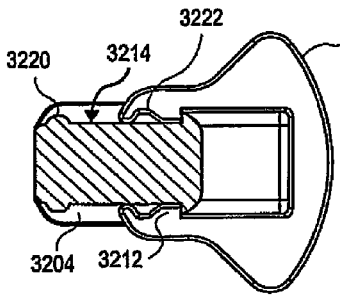


FIG. 32F



SECTION B-B
SNAP LOCK DETAIL FOR SLIDING COVER

ADHESIVE PAD AND LOCKING DEVICE SHOWN WITHOUT PAPER BACKING/CARRIER

FIG. 32E

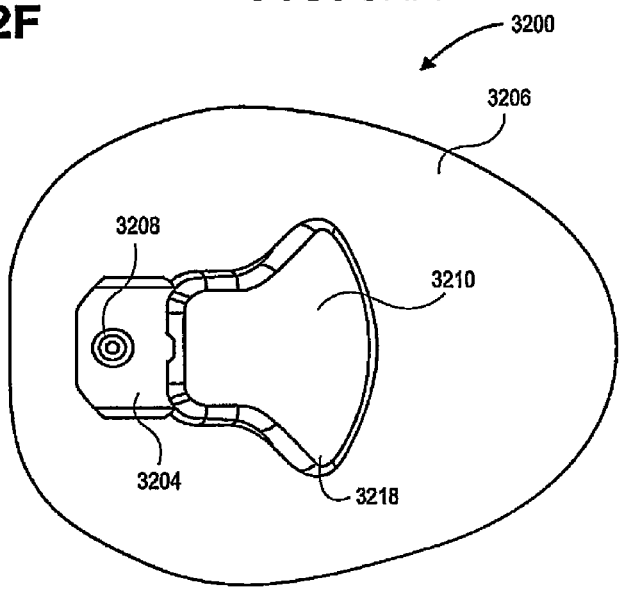


FIG. 32G

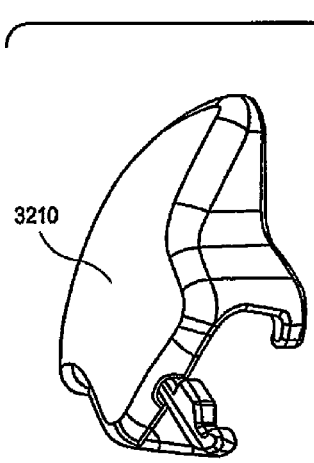


FIG. 32H

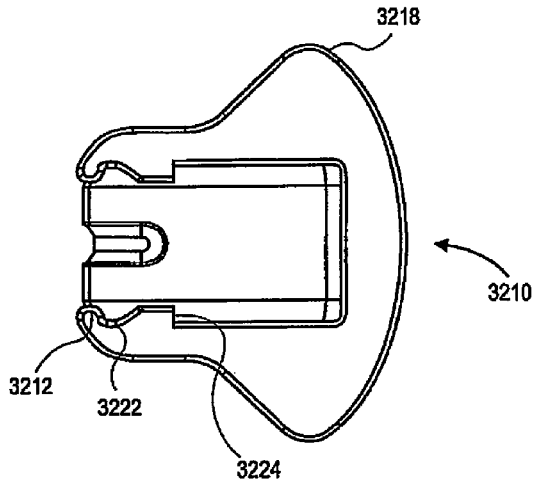


FIG. 32I

COVER COMPONENT

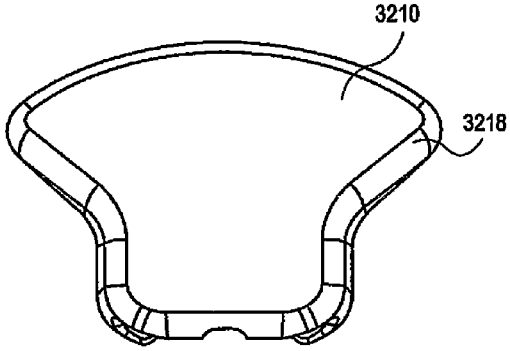


FIG. 32J

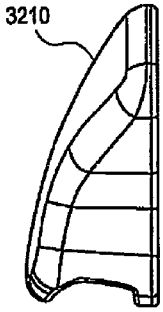


FIG. 32K

FIG. 32L

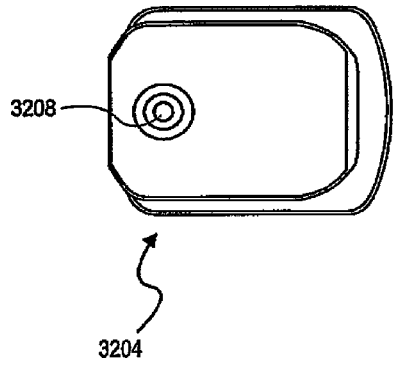
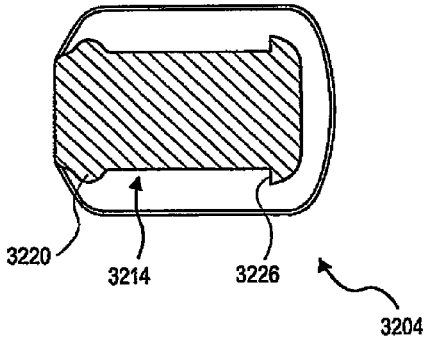


FIG. 32M



BASE COMPONENT

FIG. 32N

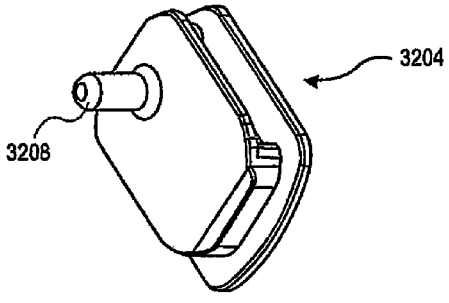
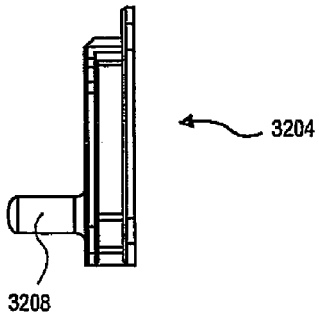
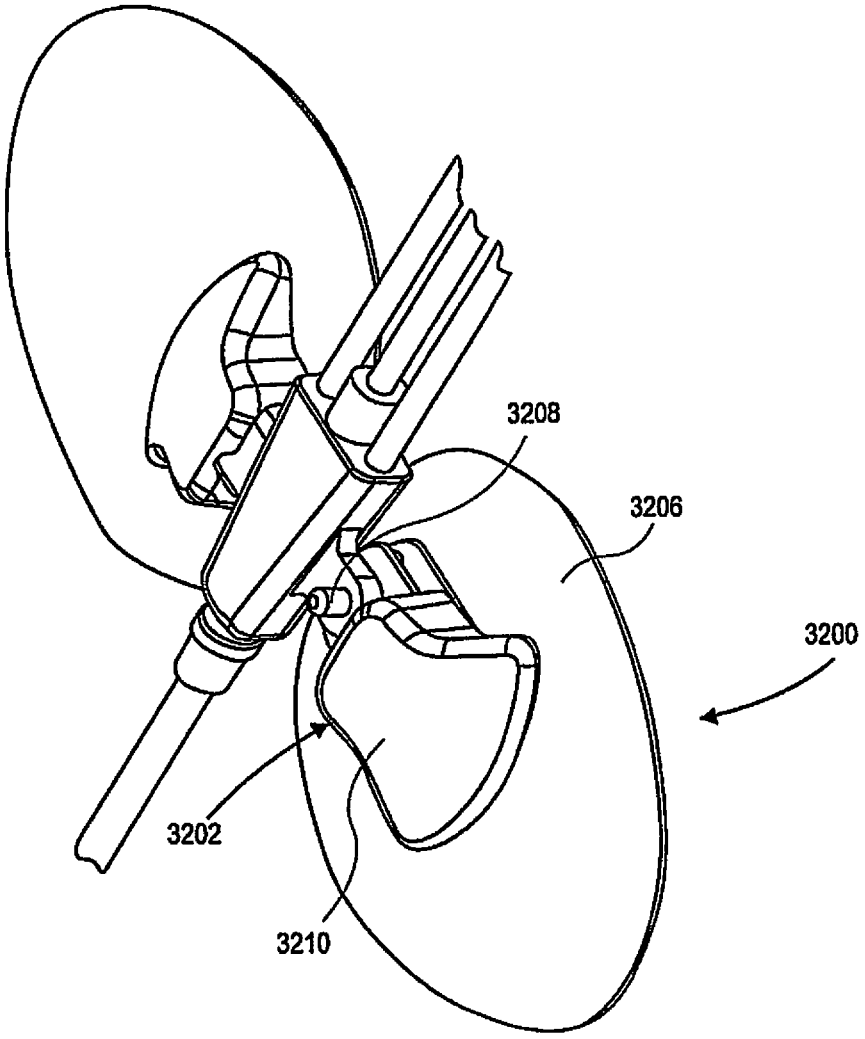


FIG. 32O





SECUREMENT DEVICE INSTALLED
ON CATHETER SUTURE TABS

FIG. 32P

CATHETER SECUREMENT DEVICES

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application Ser. No. 61/588,515 entitled "Designs and Methods for Catheter Securement Devices" and filed Jan. 19, 2012, and U.S. Provisional Patent Application Ser. No. 61/652,589 entitled "Sliding Lock Devices for Catheter Securement" and filed May 29, 2012, all of which are hereby incorporated by reference for all purposes.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

The inventions relate generally to devices for securing medical devices to a patient's body. More specifically, the inventions relate to devices for securing catheters, tubing or medical lines to a patient's skin.

BACKGROUND

Catheters, tubing and/or medical lines can be used to introduce fluids, medications or medical devices directly into the patient or to withdraw fluids from the patient. Often, it becomes desirable to maintain such catheterization over an extended period of time during the treatment of a patient. In order to keep the catheter, tubing or other medical line properly positioned for the duration of treatment, the catheter, tubing or medical line can be secured to the patient in a variety of ways. For example, the catheter, tubing or medical line can be taped to the patient.

Securing a catheter with tape upon the patient traditionally has certain drawbacks. The use of tape at the insertion site can retain dirt or other contaminant particles, potentially leading to infection of the patient. Tape also fails to limit catheter motion and, therefore, contributes to motion related complications like phlebitis, infiltration and catheter migration. Additionally, removal of taped dressings can itself cause undesired motion of the catheter upon the patient.

Taped dressings also require periodic changes. The frequent, often daily, removal and reapplication of adhesive tape to the skin of the patient can excoriate the skin in the area around the dressing. Such repeated applications of tape over the catheter or medical line can additionally lead to the buildup of adhesive residue on the outer surface of the catheter or medical line. This residue can result in contaminants adhering to the catheter itself, increasing the likelihood of infection of the insertion site. This residue can also make the catheter or medical line stickier and more difficult to handle for healthcare providers.

Accordingly, it would be desirable to provide a catheter securement device that is simple to use while providing reliable fixation of the catheter to the patient's skin.

SUMMARY OF THE INVENTION

The present invention relates systems, devices and methods for securing a catheter, tubing, medical line, or other medical device to a patient.

In some embodiments, a securement device for securing a medical device having a suture tab to a patient's body is provided. The device can include an adhesive pad having a first surface coated with an adhesive and a second surface; a tab receiving portion disposed on the second surface of the adhesive pad and along a side edge of the adhesive pad; and a downwardly extending post that extends from the top of the tab receiving portion towards the adhesive pad.

In some embodiments, the downwardly extending post is biased away from the side edge. In some embodiments, the downwardly extending post is biased at an angle between about 0 to 30 degrees from the vertical axis. In some embodiments, the downwardly extending post is configured to engage the suture tab.

In some embodiments, the adhesive pad comprises an opening under the tab receiving portion that is configured to receive the suture tab.

In some embodiments, the tab receiving portion is transparent.

In some embodiments, the securement device further includes a backing layer disposed over the adhesive, wherein the backing layer comprises a pull tab.

In some embodiments, the backing layer comprises a first portion disposed proximate the tab receiving portion and having a first pull tab, and a second portion disposed away from the tab receiving portion and having a second pull tab, wherein the first portion and the second portion are separably removable.

In some embodiments, the adhesive comprises a hydrocolloid adhesive. In some embodiments, the adhesive further includes an acrylic adhesive disposed on portions of the adhesive pad configured to be exposed to high stress.

In some embodiments, the adhesive pad has skin tone color. In some embodiments, the adhesive pad is transparent. In some embodiments, the tab receiving portion is shaped like a dome.

In some embodiments, the dome has a continuously smooth surface. In some embodiments, the dome has a flattened top portion.

In some embodiments, the tab receiving portion has a height that is less than or equal to the height of the medical device.

In some embodiments, a system for securing a medical device having a first suture tab to a patient's body is provided. The system can include a first engagement tab comprising an adhesive pad having a first surface coated with an adhesive and a second surface, a tab receiving portion disposed on the second surface of the adhesive pad and along a side edge of the adhesive pad, and a downwardly extending post that extends from the top of the tab receiving portion towards the adhesive pad, wherein the downwardly extending post is disposed through the first suture tab.

In some embodiments, the system further includes an overdressing covering at least a portion of the first engagement tab and the medical device.

In some embodiments, the system further includes a second engagement tab that is secured to a second suture tab on the medical device, wherein the second engagement tab is secured independently of the first engagement tab.

In some embodiments, the first engagement tab is pivotably engaged with the first suture tab and the second engagement tab is pivotably engaged with the second suture tab.

In some embodiments, a system for securing a medical device to a patient's body is provided. The system can include an adaptor having a first suture tab, wherein the adaptor is removably disposed over a portion of the medical device; and a first engagement tab comprising an adhesive pad having a

first surface coated with an adhesive and a second surface, a tab receiving portion disposed on the second surface of the adhesive pad and along a side edge of the adhesive pad, and a downwardly extending post that extends from the top of the tab receiving portion towards the adhesive pad, wherein the downwardly extending post is disposed through the first suture tab.

In some embodiments, the system further includes an overdressing covering at least a portion of the first engagement tab, adaptor and the medical device.

In some embodiments, the system further includes a second engagement tab that is secured to a second suture tab on the adaptor, wherein the second engagement tab is secured independently of the first engagement tab.

In some embodiments, the adaptor comprises a channel for receiving the portion of the medical device. In some embodiments, the channel comprises a deformable liner. In some embodiments, the deformable liner is elastic and reversibly deformable. In some embodiments, the deformable liner is made of foam.

In some embodiments, a method of securing a medical device having a first suture tab to a patient's body is provided. The method can include providing a first engagement tab comprising an adhesive pad having a first surface coated with an adhesive and a second surface, a tab receiving portion disposed on the second surface of the adhesive pad and along a side edge of the adhesive pad, and a downwardly extending post that extends from the top of the tab receiving portion towards the adhesive pad; disposing the downwardly extending post through the first suture tab; and adhering the adhesive pad to the patient's body.

In some embodiments, the system further includes disposing an overdressing over at least a portion of the first engagement tab and medical device.

In some embodiments, the system further includes providing a second engagement tab and securing the second engagement tab to a second suture tab on the medical device, wherein the second engagement tab is secured independently of the first engagement tab.

In some embodiments, the system further includes removing a first portion of a backing layer disposed over the adhesive, wherein the first portion of the backing layer covers a portion of the adhesive proximate the tab receiving portion.

In some embodiments, the system further includes positioning the first engagement tab on the patient's body after the first portion of the backing layer is removed.

In some embodiments, the system further includes removing a second portion of the backing layer after the first engagement tab is positioned on the patient's body.

In some embodiments, a securement device for securing a medical device having a suture tab to a patient's body is provided. The device can include an adhesive pad having a first surface coated with an adhesive and a second surface; a base disposed on the second surface; an upwardly extending post that extends from the base and away from the adhesive pad, wherein the post is configured to engage the suture tab; and a cover that is slidably attached to the base portion and configured to have a closed configuration that covers the post and an open configuration that exposes the post.

In some embodiments, the cover is reversibly secured to the slot by a locking mechanism.

In some embodiments, the base has a slot and the cover has a rail which is slidably disposed in the slot.

In some embodiments, the locking mechanism generates a tactile indicator when the cover is moved between the closed configuration and open configuration. In some embodiments, the locking mechanism generates an audible indicator when the cover is moved between the closed configuration and open configuration. In some embodiments, the locking mechanism comprises a rounded protrusion disposed within the slot and a complementary rounded indentation disposed on the rail. In some embodiments, the locking mechanism comprises a rounded protrusion disposed on the rail and a complementary rounded indentation disposed within the slot.

In some embodiments, the device further includes a backing layer disposed over the adhesive, wherein the backing layer comprises a pull tab. In some embodiments, the backing layer comprises a first portion disposed proximate the base and having a first pull tab, and a second portion disposed away from the base and having a second pull tab, wherein the first portion and the second portion are separably removable.

In some embodiments, a system for securing a medical device to a patient's body is provided. The system can include an adaptor having a first suture tab, wherein the adaptor is removably disposed over a portion of the medical device; and a first securement device comprising an adhesive pad having a first surface coated with an adhesive and a second surface, a base disposed on the second surface, an upwardly extending post that extends from the base and away from the adhesive pad, and a cover that is slidably attached to the base portion and configured to have a closed configuration that covers the post and an open configuration that exposes the post, wherein the post is disposed through the first suture tab.

In some embodiments, the system further includes an overdressing covering at least a portion of the first securement device, adaptor and the medical device.

In some embodiments, the system further includes a second securement device that is secured to a second suture tab on the adaptor, wherein the second securement device is secured independently of the first securement device.

In some embodiments, the adaptor comprises a channel for receiving the portion of the medical device. In some embodiments, the channel comprises a deformable liner. In some embodiments, the deformable liner is elastic and reversibly deformable. In some embodiments, the deformable liner is made of foam.

In some embodiments, a method of securing a medical device having a first suture tab to a patient's body is provided. The method can include providing a first securement device comprising an adhesive pad having a first surface coated with an adhesive and a second surface, a base disposed on the second surface, an upwardly extending post that extends from the base and away from the adhesive pad, and a cover that is slidably attached to the base portion and configured to have a closed configuration that covers the post and an open configuration that exposes the post; disposing the post through the first suture tab; sliding the cover to the closed configuration; and adhering the adhesive pad to the patient's body.

In some embodiments, the method further includes disposing an overdressing over at least a portion of the first securement device and medical device.

In some embodiments, the method further includes providing a second securement device and securing the second securement device to a second suture tab on the medical device, wherein the second securement device is secured independently of the first securement device.

In some embodiments, a securement device for securing a medical device to a patient's body is provided. The device can include an adhesive pad having a first surface coated with an adhesive and a second surface; and a vacuum formed blister pack disposed on the second surface and shaped to conform to a portion of the medical device.

In some embodiments, the vacuum formed blister pack is molded to the portion of the medical device.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a perspective view of one embodiment of a modular catheter securement device.

FIG. **2** is a perspective view of another embodiment of a modular catheter securement device.

FIG. **3** is a cross-sectional view of an embodiment of an engagement tab of a modular catheter securement device.

FIGS. **4**A-**5**B illustrate other embodiments of the engagement tab.

FIGS. **6**-**10** illustrate embodiments of various adaptors that provide suture tabs to other medical devices.

FIGS. **11**A-**11**E illustrate the securement of catheters with various embodiments of the adaptors and engagement tabs.

FIGS. **12**A-**12**E illustrate various embodiments of a securement device having a balloon.

FIGS. **13**A-**13**F illustrate an embodiment of the securement device having a butterfly wrap configuration.

FIGS. **14**A-**14**D illustrate an embodiment of the securement device using a gel pad.

FIGS. **15**A-**15**G illustrate various embodiments of securement devices using a hook and loop fastener.

FIG. **16** illustrates an embodiment of a securement device using snap on posts.

FIG. **17** illustrates an embodiment of a securement device using staked posts.

FIG. **18** illustrates an embodiment of a quick feed strap slot.

FIG. **19** illustrates an embodiment of a securement device using magnets.

FIG. **20** illustrates another embodiment of a securement device using downwardly extending posts.

FIG. **21** illustrates yet another embodiment of a securement device using downwardly extending posts.

FIGS. **22**A-**22**C illustrates an embodiment of a securement device using tear-away pads.

FIG. **23** illustrates an embodiment of a securement device using a strap and buckle over a nested hub to secure a catheter.

FIGS. **24**A and **24**B illustrate an embodiment of a securement device having wire hooks.

FIG. **25** illustrates an embodiment of a securement device made from a vacuum formed blister pack.

FIGS. **26**A-**26**D illustrate an embodiment of a securement device formed from a wire loop.

FIGS. **27**A-**27**E illustrate an embodiment of a securement device having a sheath and hooks.

FIGS. **28**A-**28**E illustrate an embodiment of a securement device having a snap-on feature and an expandable anchor.

FIGS. **29**A and **29**B illustrate another embodiment of a securement device having an having an expandable anchor.

FIGS. **30**A and **30**B illustrate yet another embodiment of a securement device having an expandable anchor.

FIGS. **31**A-**31**C illustrate an embodiment of a securement device having anchors configured for subdermal penetration.

FIGS. **32**A-**32**P illustrate an embodiment of a securement device having a slide-locking feature.

DETAILED DESCRIPTION

FIGS. **1** and **2** illustrate an embodiment of a modular catheter securement system and/or device **100** that can be used to secure a catheter **102**, tube or medical line having a catheter hub **104** with suture tabs **106** to a patient's skin. The securement device **100** includes independent and modular engagement tabs **108** that are configured to engage the suture tabs **106** and thereby secure the catheter hub **106** to the patient's skin. For a typical catheter with two suture tabs **106**, the securement device **100** includes two engagement tabs **108**. In general, the securement device **100** has an equal number of engagement tabs **108** as there are suture tabs **106**. Since the engagement tabs **108** are independent and modular, more or fewer engagement tabs **108** can be used as needed.

The engagement tab **108** has a tab receiving portion **110** that is attached to an adhesive pad **112**. The tab receiving portion **110** can have a cavity and an opening along the side facing the catheter hub **104** and along the bottom of the engagement tab **108** for receiving the suture tab **106**. The tab receiving portion **110** can include a post **114** sized and shaped for engaging and passing through the hole in the suture tab **106**. The tab receiving portion **110** can also have a base portion **111** that can be attached to the adhesive pad **112** and that provides stability to the tab receiving portion **110**. As shown in FIG. **3**, the post **114** can be made integral with the tab receiving portion **110** and can extend downwards from the top of the tab receiving portion **110** towards the bottom opening **116** of the tab receiving portion **110**. The post **114** can be biased away from side opening **118** of the tab receiving portion **110**, such that the distal end **120** of the post **114** is biased away from the suture tab **106** when the tab receiving portion **110** is engaged with the suture tab **106**. The biased post **114** aids in preventing or reducing the likelihood of accidental disengagement of the tab receiving portion **110** from the suture tab **106** when the catheter **102** or catheter hub **104** is pushed downwards into the patient's skin. As the catheter **102** or catheter hub **104** is pushed downwards, the biased post **114** can exert an outwards and/or upwards force on the suture tab **106** that provides resistance to further downwards movement of the catheter **102** or catheter hub **104**, thereby preventing and/or resisting accidental disengagement of the tab receiving portion **110** from the suture tab **106**. In some embodiments, the post **114** can be angled between about 0 to 30 degrees, 0 to 25 degrees, 0 to 20 degrees, or 0 to 15 degrees from the vertical axis. In some embodiments, the post **114** is angled at least about 1, 2, 3, 4, 5, 10, 15, 20, 25, or 30 degrees from the vertical axis. In some embodiments, the post **114** can be angled less than about 5, 10, 15, 20, 25, or 30 degrees from the vertical axis. About or approximately as used herein can mean within 10%, 20%, or 30%, for example. In some embodiments, the post **114** can be tapered such that the distal end of the post **114** has a smaller diameter than the proximal portion of the post **114**. In some embodiments, the post **114** is not tapered and has a constant diameter. In some embodiments, the distal end of the post **114** can include a barb, ball, or other retaining mechanism to improve retention of the post within the hole of the suture tab.

In some embodiments, the tab receiving portion **110** can be made of a flexible or semi-rigid material that can bend or flex in response to applied stress. The added flexibility enables the engagement portion **108** to absorb force exerted on the engagement portion **108**, thereby reducing the force exerted on the catheter **102** and/or catheter hub **104** which reduces the risk of accidental dislodgement of the catheter **102** from the patient.

In some embodiments, the catheter **102** can include a plurality of lines **130** that can be secured to the patient with a line management device **140**. The line management device **140** can comprise a body portion **142** with one or more channels **144** that can be disposed parallel to one another. The channels

144 are sized and shaped to receive the lines 130. The body portion 142 can be disposed on a adhesive pad 146 with features similar to that described herein.

As illustrated in FIG. 4, the adhesive pad 112 can include a peelable backing layer 122 to cover the adhesive on the adhesive pad 112. The backing layer 122 can have a pull tab 124 for removing the backing layer 122 from the adhesive pad 112 and thereby exposing the adhesive on the adhesive pad 112. In some embodiments, the backing layer 122 can be divided into multiple pieces, each with a separate tab 124 to facilitate peeling. For example, the backing layer 122 can have a first portion that covers the area around the tab receiving portion 110 and a second portion away from the tab receiving portion 110. Having two portions allows only a relatively small portion of the adhesive to be exposed while positioning the securement device on the patient, which may allow easier repositioning of the securement device. In other embodiments, the backing layer 122 can be formed of a single piece with a single tab 124 to facilitate peeling. The backing layer 122 can be removed before the adhesive pad 112 is pressed into contact with the patient's skin. In some embodiments, the backing layer 122 can be removed prior to inserting the post 114 through the hole in the suture tab 106. In other embodiments, the backing layer 122 can be removed after inserting the post 114 through the hole in the suture tab 106.

In some embodiments, the adhesive pads 112 can use a combination of an acrylic adhesive for the high stress points and a hydrocolloid adhesive for long term securement and comfort. In some embodiments, the adhesive pads 112 can use either the acrylic adhesive or the hydrocolloid adhesive. The backing layer 122 can be made from paper, plastic or any other suitable material that can be peeled from the adhesive. In some embodiments, a two or more securement devices 100 can be disposed on a single backing layer 122 that can be perforated or scored between the adhesive pads 122 of the securement devices 100 to allow the securement devices 100 to be held together during packaging and easy separation of the securement devices 100 from each other before use. The adhesive pad 112 substrate can be a skin tone fabric or a clear material that allows for the skin color to show through in order to minimize the visual impact of the device on the patient who may have to endure the catheter for many days. The adhesive pad 112 can be made of a flexible material so that it can conform to that geometry of the patient's body.

One unique feature of this design is that the securement device 100 comes in modular parts, such as the modular engagement tabs 108 that are each comprised of a tab receiving portion 110 on an adhesive pad 112. The engagement tab 108 is attached to each suture tab 106 on each side of the catheter hub 104 and adhered to the patient's skin. Because the engagement tabs 108 are separate and modular, the securement device can accommodate catheter hubs 104 of any width that uses suture tabs 106. This enables a universal fit for many catheter styles or brands.

Attaching the engagement tab 108 to the suture tab 106 on the catheter 102 is a simple maneuver that can be accomplished by simply engaging the post 114 of the engagement tab 108 into the hole of the suture tab 106 from the top down. This requires very little manipulation of the indwelling catheter 102 which is a priority of users. Since the modular engagement tabs 108 are independent, each engagement tab 108 can be optimally positioned sequentially according to the patient anatomy. This lends flexibility of placement which is another important feature for users. In addition, in some embodiments, the fit of the post 114 within the hole of the suture tab 106 can leave some room for the post 114 to pivot within the hole, which can further enhance the ability of the modular securement system to conform to the variable geometry of the patient's body. This can be accomplished, for example, by making the post 114 have a smaller diameter than the hole of the suture tab 106. The ability of the engagement tabs 108 to pivot on the suture tab 106 allows the engagement tabs 106 and catheter hub 104 or other device to each lie within different planes if needed, which aids the system in conforming to the patient's body. The adhesive pads 112 of each engagement tab 108 can be trimmed to any shape if needed. Once both engagement tabs 108 are in place, the catheter 102 is held extremely well by the adhesive pads 112. The shape and placement of adhesive provides resistance to lateral and upwards pulling of the catheter 102 or tubing, thereby ensuring proper securement of the catheter 102 to the patient.

In some embodiments, the engagement tab 108 can be dome shaped with curved surfaces, as illustrated in FIGS. 1 and 2. The dome in FIG. 2 has a continuously smooth surface while the dome in FIG. 1 has a non continuous smooth surface with a flattened top portion. In some embodiments, a dome with a continuously smooth surface can be more easily covered with an overdressing such that pockets of air trapped between the overdressing and dome are reduced. The engagement tab 108 can be made of a transparent material, such as a transparent plastic, that allows the user to visualize the post 114 through the walls of the dome forming the tab receiving portion 110. The post 114 can be made opaque so that it is easier to visualize. For example, the post can be coated or made from an opaque material. The discrete shape and size of the dome permits full visualization of the catheter hub and skin entry point. The engagement tab 108 can have a low profile which enables smooth placement of overdressings, such as Tegaderm™, over the catheter 102, catheter hub 104, and/or securement devices 100. For example, the engagement tab 108 can have a height that is less than or equal to the height of the catheter 102 and/or the catheter hub 104. This results in a securement device 100 with optional overdressing that is no higher than the catheter 102 or catheter hub 104 itself with no obtrusive bumps, housings, catch points and the like for maximum patient comfort while reducing the likelihood of accidentally snagging and dislodging or removing the catheter 102, catheter hub 104 and/or securement device 100.

In some embodiments, as illustrated in FIGS. 4A-4C, the engagement tab 108 can have an alternative tab receiving portion 111. Rather than a dome shaped tab receiving portion 110 as shown in FIGS. 1-3, the engagement tab 108 can have a tab receiving portion 111 formed from an angled strip of material with a post 114 extending downwards from the distal end of the strip. As above, the post 114 can be biased inwards and away from the distal end of the strip. The strip can be straight or curved. In curved embodiments, the curve can be convex, concave, or a combination of convex and concave curves. As above, the strip-like engagement tab 108 can be flexible or semi-rigid, which enables to engagement tab 108 absorb force exerted on the engagement tab 108, which reduces the force exerted on the catheter 102 and/or catheter hub 104. One difference between the strip-like engagement tab and the dome-like engagement tab is that the post 114 is shielded by the dome and accessible in the strip embodiment. In some embodiments, it can be easier to manipulate the post 114 without detaching the adhesive pad 112 from the skin in the strip embodiment in the event that the post 114 becomes dislodged and needs to be repositioned through the suture tab 106. In some embodiments, a dome or enclosure can be placed over the strip-like engagement tab 108 to form a hybrid embodiment.

An alternative embodiment of the engagement tab is illustrated in FIGS. **5**A and **5**B. The engagement tab **110**B is can be form an enclosure like the dome embodiment, except that the shape of the enclosure can be rectangular or square. The engagement tab **110**B can have the other features described for the dome embodiment, such as having a biased post **114** and be made from a transparent material. In some embodiments, the enclosure can be partially rectangular or square and partially curved.

In some embodiments, the catheter and/or catheter hub may not have suture tabs to which the securement device can be attached. In this situation, adaptors can be used to provide suture tabs to the catheter. Various adaptors can be used to fit over catheters, luer connectors, standard catheter hubs, custom catheter hubs, and other catheter related parts near the insertion point. The combination of the modular securement device with an adaptor allows the securement device to be used in a large variety of catheters

For example, FIG. **6** illustrates one embodiment of an adaptor **200** that can be fastened to a luer connector, catheter, or other generally tubular catheter related part. The adaptor **200** can have an adaptor body **202** and a channel **204** disposed through or within the adaptor body **202** for receiving the luer connector, catheter, or other generally tubular catheter related part. The adaptor body **202** can have or rest on a base **206** that is configured to be placed on the patient's skin. The base **206** can include suture tabs **208** that extend transversely away from the channel **204** to which engagement tabs **108** can be fastened to as described above.

In some embodiments, the channel **204** or the longitudinal axis of the channel **204** can be angled downwards with respect to the base **206** or plane defining the base **206**. For example, the channel **204** can be angled downwards between about 0 to 5, 0 to 10, 0 to 15, 0 to 20, 0 to 25, 0 to 30 degrees, 0 to 35, 0 to 40, or 0 to 45 degrees with respect to the base. The angled channel **204** allows the distal end of the catheter to be pointed towards the skin, thereby allowing the user to more easily control the angle of insertion of a needle or the catheter into the patient's body. Control of the angle of insertion along with the distance of insertion is important in preventing or reducing the forces that the indwelling device exerts on the patient's tissue, which can help reduce damage to the tissue.

In some embodiments, the base **206** can have an access slot **210** that provides access to the channel **204**. The access slot **210** can run parallel to the channel **204**. In some embodiments, the access slot **210** can have a width that is less than the diameter of the channel **204**, which allows the channel **204** to securely retain the inserted device without the device inadvertently falling out. In some embodiments, the access slot **210** tapers such that the width of the access slot **210** adjacent to the channel **204** is narrower than the diameter of the channel **204**, while the diameter of the access slot **210** gradually increases in width as it moves away from the channel **204**, as illustrated in FIG. **8**, for example. In some embodiments, the adaptor body **202** can have a plurality of alignment slots **212** that are oriented transversely to the axis of the channel **204**. These alignment slots **212** can function as alignment features by restraining a tab on the luer connector, catheter, or other generally tubular catheter related part, to restrain the axial movement of the catheter within the adaptor **200**. In some embodiments, the adaptor body **204** does not have alignment slots **212**.

In some embodiments, the channel **204** can be coated or covered with a liner that can provide a gripping surface to secure the inserted device. The liner can be soft, elastic, spongy, resilient and/or reversibly deformable to conform to the inserted device and to allow the adaptor **200** to secure a wider variety of inserted devices. In some embodiments, the liner can be made of a foam or sponge material. In some embodiments, the liner can be expandable and filled with a liquid, gel and/or a gas. The liner can be included in any of the adaptor embodiments described herein.

FIG. **7** illustrates another embodiment of an adaptor **220** having an adaptor body **222** that encloses a channel **224**. The base **226** can be integral with the adaptor body **222**. Suture tabs **228** can be provided that extend from the base **226**, and to which engagement tabs **108** can be secured. In some embodiments, including other embodiments described herein, the suture tabs **228** can be offset from the base **226**. In the illustrated embodiment, the adaptor body **222** can be made of two sections **230**, **231** that together define the channel **224** and can be connect together by a hinge **232** that allows the two sections **230**, **231** to be separated, thereby exposing the channel **224** and allowing a device to be inserted into the channel **224**. A locking mechanism **234**, such as a latch for example, can be used to reversibly secure the two sections **230**, **231** together. As described above, the channel **224** can be angled with respect to the base **226**. An alignment feature **236** on the top surface of the adaptor body **222** can indicate to the user which direction in which to insert the device into the channel. The alignment feature **236** can also be included in the other adaptor embodiments described herein.

FIG. **8** illustrates another embodiment of an adaptor **240**. The adaptor **240** has an adaptor body **242** that defines a channel **244** for receiving an inserted device as described herein. As described herein, the channel **244** can be angled with respect to the base **246**. The body **242** can have a base **246** and suture tabs **248** that are offset from the base **246**. The offset can be between about 0 to 2, 0 to 4, 0 to 6, 0 to 8, or 0 to 10 mm. An access slot **250** can be provided on the bottom of the adaptor body **242** to provide access to the channel **244**. As described above, the access slot **250** can have a taper such that it is narrower than the diameter of the channel **244** at a point adjacent to the channel **244**, but progressively widens as the access slot **250** moves away from the channel **244**. This configuration provides a larger target zone for insertion of the inserted device into the channel **244**, and also acts to funnel the inserted device to the channel **244**, thereby facilitating insertion of the inserted device into the channel **244**. The channel **244** can have a liner **252** for gripping the inserted device, as further described herein in other embodiments. For example, the liner **252** can be soft, elastic, and/or deformable, which allows the liner **252** to conform to inserted devices of a variety of shapes and sizes.

FIG. **9** illustrates another embodiment of an adaptor **260** that can be used to provide suture tabs to a catheter, luer adapter, and the like. The adaptor **260** can include an adaptor body **262** that encircles or partially encircles a channel **264**. The adaptor body **262** can have a base **266**, which can be integral to the adaptor body **262**. The suture tabs **268** can extend from the base **266** and also be integral to the base **266**. A slot **270** can be formed in the base **266** to provide access to the channel **264** and to divide the base **266** into two separable parts. The body **262** can be made of a flexible material, such as rubber or another flexible elastomeric polymer, such that the slot **270** can be widened by deforming the body **262**. For example, force can be applied downwards on the top portion of the body **262** while an upwards force can be applied to the suture tabs **268** in order to widen the slot **270** so that the adaptor **260** can be placed over the inserted device. In some embodiments, the slot **270** can be narrow or closed in the unstressed configuration such that the channel **264** substantially encloses an entire circumference. In other embodiments, the slot **270** can be wider, such as in the embodiments

disclosed above, so that the channel **264** is configured to encircle only a portion of the inserted device, which is typically at least 50% of the circumference of the inserted device. As above, the channel **264** can be angled with respect to the base, and the channel **264** can include a liner.

FIG. **10** illustrates another embodiment of an adaptor **280** that can be used to secure a specialty catheter or hub, such as neural block catheter, for example. The adaptor **280** can include a adaptor body **282** having a first portion **284**, a second portion **286** and a third portion **288** disposed between the first portion **284** and the second portion **286**. The first portion **284** can include an open channel **290** formed at the top of the first portion **284**, such that the inserted device can be inserted into the channel **290** from above by pushing the inserted device downwards into the channel **290**. The second portion **286** also includes a second open channel **292** formed at the top of the second portion **286**. The second channel **292** may have the same or may have a different cross-sectional profile than the first channel **290**. In some embodiments, both the first channel **290** and the second channel **292** have arcuate, semi-circular cross-sectional profiles. In some embodiments, the length of the first channel **290** is greater than the length of the second channel **292**. In some embodiments, the length of the first channel **290** is the same as or greater than the length of the second channel **292**. The third portion **288** can be a flat depression with a surface that lies below the lowest point of the first channel **290** and the second channel **292**. In some embodiments, the suture tabs **294** can extend outwards from the first portion **286** and can be offset from the base **296** of the adaptor body **282**. As described above, the first channel **290** and/or the second channel **292** can be angled with respect to the base, and a liner can be added to either channel.

FIGS. **11**A-**11**E illustrate the attachment of the adaptors described herein to luer adaptors or specialty hubs. For example, FIGS. **11**A and **11**B illustrate the attachment of the adaptor **200** described in FIG. **6** with a luer adaptor and the attachment of engagement tabs **108** to the suture tabs **208** provided by the adaptor **200**, thereby securing the catheter in place. In practice, the adaptor **200** can first be placed over the luer adaptor **300** by, for example, snapping the luer adaptor **300** through the access slot **210** and into the channel **204** in order to provide suture tabs **208** to the luer adaptor **300**. A securement device **100** can then be attached to the suture tabs **208** as described above. A line management device **302** can be used to secure the lines of the catheter.

FIG. **11**C illustrates the attachment of the adaptor **220** described in FIG. **7** to a luer adaptor **300**. As described above, the adaptor **220** can be opened into two pieces and then locked over the luer adaptor **300** to provide suture tabs **228** to the luer adaptor. A securement device **100** can then be attached to the suture tabs **228** as described above. A line management device **302** can also be used to secure the lines of the catheter.

Similarly, FIGS. **11**D-**11**E illustrate the attachment of the adaptors described in FIGS. **8**-**10** to either a luer adaptor **300** or a specialty hub **310** to provide suture tabs to the luer adaptor **300** or specialty hub **310**. One the suture tabs are provided, a securement device **100** can be attached to the suture tabs as described above. A line management device **302** can also be used to secure the lines of the catheter. In some embodiments, the line management device **302** can be attached to top portion of the adhesive pad **112**.

Alternative Securement Devices

FIGS. **12**A-**12**E illustrate another embodiment of a securement device **1200**. The securement device **1200** includes an adhesive pad **1202** and an inflatable tube **1204** disposed on or integral to the adhesive pad **1202**. The inflatable tube **1204** can have an inflation port **1206** that can be used to inflate the inflatable tube **1204** with a gas or liquid. In some embodiments as illustrated in FIGS. **12**D and **12**E, the inflatable tube **1204** further includes a longitudinal split **1208** that allows the inflatable tube **1204** to partially unfurl, which can make insertion or removal of the catheter **1210** through the inflatable tube **1204** easier. To secure the catheter **1210**, the catheter **1210** can be inserted through the inflatable tube **1204** and then the inflatable tube **1204** can be inflated to compress the catheter **1210** within the inflatable tube **1204**. As the inflatable tube **1204** is inflated, the diameter of the inflatable tube **1204** decreases until contact is made with the catheter **1210**.

FIGS. **13**A-**13**F illustrate another embodiment of a securement device **1300**. The securement device **1300** includes an adhesive pad **1302** and an adhesive wrap **1304** that is attached to the adhesive pad **1302**. The adhesives on the adhesive pad **1302** and the adhesive wrap **1304** can be disposed on the nonadjacent surfaces of each so that the adhesive pad **1302** can be attached to the patient's skin and the adhesive wrap **1304** can be wrapped over a catheter **1306** or other device placed on top of the adhesive wrap **1304**. The adhesive wrap **1304** can be flexible so that it can be easily wrapped over and around the catheter **1306**. The adhesive wrap **1304** can be either permanently or reversibly attached to the adhesive pad **1302**. Reversible attachment can be accomplished by using adhesives, hook and loop fasteners, latches, clips and the like. Generally, the middle portion **1308** of the adhesive wrap **1304** is attached to the adhesive pad **1302** such that the adhesive wrap **1304** has two wings **1310** than can be used to wrap around the catheter. Both the adhesive wrap **1304** and the adhesive pad **1302** can be covered by one or more backing layers which can be peeled off to expose the adhesive.

FIGS. **14**A-**14**D illustrate another embodiment of a securement device **1400**. The securement device **1400** includes an adhesive pad **1402** and a gel pad **1404** disposed on the adhesive pad **1402**. An adhesive film **1406** can be disposed over the gel pad **1404** to secure a catheter **1408** or other device that has been placed on the gel pad **1404**. The gel pad **1404** can provide compression around the catheter **1408** and can further be coated or impregnated with an antimicrobial agent. The adhesive film **1406** can be transparent and can be removably adhered over the gel pad **1404** and catheter **1408**.

FIGS. **15**A-**15**G illustrate additional embodiments of securement devices involving a hook and loop fastener. For example, FIG. **15**A illustrates a securement device **1500** having an adhesive pad **1502** with an adhesive on one side to bind to skin and loops **1508** or hooks on the other side. A flexible covering **1504** has hooks **1510** or loops complementary to the adhesive pad **1502** disposed on one side of the flexible covering **1504**. A molded cover **1506** can optionally be used to cover the catheter or catheter hub or other device that is placed on the adhesive pad **1502**. The molded cover **1506** can be shaped and sized to conform to the catheter, catheter hub or other device. After the device is placed on the adhesive pad **1502**, the flexible covering **1504** is fastened to the adhesive pad **1502** over the device using the hook and loop fastener. FIG. **15**G illustrates another embodiment of a securement device that is similar to the embodiment described in FIG. **15**A. The difference is that the molded cover **1506** shown in FIG. **15**A is replaced with a base **1590** have two posts **1592** that can engage the holes in the suture tabs of a catheter hub.

FIG. **15**B illustrates another embodiment of a securement device **1520**. The securement device **1520** can have an adhesive pad **1522** and a base **1524** disposed on the adhesive pad **1522**. The base **1524** can optionally have posts **1526** sized and spaced to fit through the suture tabs on a catheter hub. One side of the base **1526** can have a slot **1528** for receiving a strap **1530** that is attached to the other side of the base **1526**. A

portion of one side of the strap **1530** can be covered in hooks **1532** and another portion of the same side of the strap can be covered in loops **1534**. To secure the catheter hub, the suture holes of the catheter hub are disposed over the posts **1526**, if present, and the strap **1530** is passed over the catheter hub and through the slot **1528**. The strap **1530** is then tightened and can be looped back on itself such that the hooks and loops on the strap **1530** are engaged to secure the strap **1530**.

FIGS. **15**C and **15**D illustrate a molded capture cover **1540** with strap slots **1542** and a catheter hub **1560** with molded in strap slots **1562**, respectively, that can be used with the adhesive pads illustrated in FIGS. **15**E and **15**F. FIG. **15**E illustrates an adhesive pad **1550** having two attached straps **1552**. The straps **1552** can be spaced apart to match the separation of the strap slots in the molded capture cover or catheter hub. One side of each strap **1552** can be covered with a loop **1554** or hook material while an area of the adhesive pad **1550** adjacent or proximate the strap **1552** is covered with a complementary hook **1556** or loop material to secure the strap **1552**. The straps **1552** are designed to be folded outwards towards the ends of the adhesive pad **1550**. FIG. **15**F illustrates a two piece embodiment of the adhesive pad illustrated in FIG. **15**E where the middle portion between the straps has been removed to form two adhesive pads **1550**, each with a single strap **1552** located on one edge of the adhesive pad **1550**. To secure the molded capture cover **1540** or catheter hub **1560** to the adhesive pad **1550**, the strap **1552** is passed through the strap slot **1542**, **1562** and then looped back on itself so that the hook and loop material engage each other. The two piece adhesive pads **1550** can be used with a wide variety of molded capture covers and molded catheter hubs of different sizes as long as each have strap slots.

FIG. **16** illustrates a securement device **1600** having an adhesive pad **1602**, a base **1604** disposed on the adhesive pad **1602**. The base **1604** can have a pair of snap-on posts **1606** that can snap into the holes on the suture tabs **1608** of a catheter hub **1610**. The snap-on posts **1606** can be made by cutting a post in half and then separating the two halves by a small distance such that gap is formed between the two halves. The posts **1606** can have tapered end portions that are wider than the post stem, such that insertion of the posts **1606** into the holes forces the two halves of each post **1606** together until the tapered end portions pass through the hole, after which the post halves can once again separate. The width or diameter of the two tapered end portion halves when separated can be slightly larger than the hole diameter, and the width or diameter of the two tapered end portion halves when pushed together can be smaller than the hole diameter. This allows the tapered end portion to pass through the hole while providing a restraining effect after passing through the hole.

FIG. **17** illustrates an embodiment of a post **1700** having a hole **1702** oriented transversely to the post axis. The hole **1702** can be located proximate the free end of the post **1700**. A pin **1704** or stake can be inserted through the hole **1702** in order to secure a suture tab that has been placed over the post **1700**. The pins **1704** can be connected together or can be independent.

FIG. **18** illustrates an embodiment of a quick feed strap slot **1800**. The quick feed strap slot **1800** has an opening **1802** that is narrower than the slot **1800** and in communication with the slot **1800** that provides access to the slot **1800** from the side of the hub **1804** or device. A strap **1806** can be pinched together to narrow the width of the strap **1806**, which can be then passed through the opening **1802** and into the slot **1800**.

FIG. **19** illustrates an embodiment of a securement device **1900** that uses a base **1902** with one or more magnets **1904** to secure a molded cover **1906** or molded hub with complementary magnets **1908**. The attractive force between the complementary magnets located on the base and the molded cover secures the parts together.

FIG. **20** illustrates another embodiment of a securement device **2000** that has an adhesive pad **2002** and slot retainer **2004** disposed on the adhesive pad **2002**. The slot retainer **2004** can have a housing **2006** with a slot **2008** located on the top of the housing **2006**. The slot retainer **2004** and two openings **2010**, **2012** to pass the catheter **2020** and lines **2022**. The housing **2006** can also have downward extending posts **2014** for engaging the holes **2024** suture tabs of the catheter hub **2026**. The housing **2006** is designed to be placed over the catheter hub **2026** with the posts **2014** engaging the holes in the suture tabs. In some embodiments, a portion of the hub can extend through the slot **2008** in the housing **2006**.

FIG. **21** illustrates another embodiment of a securement device **2100** with a molded cover **2102** having a pair of downwardly extending posts **2104** and two flexible wings **2106**. If the wings **2106** are coated with an adhesive, the wings **2106** can be directly adhered to the patient's skin. If the wings **2106** are covered with a hook and loop fastener material, the wings **2106** can be fastened to an adhesive pad with complementary hook and loop fastener material. The posts **2104** can be inserted into the holes of suture tabs.

FIGS. **22**A-**22**C illustrate another embodiment of a securement device **2200** having an adhesive pad **2202** with tear-away side portions **2204**. The bottom surface of the adhesive pad **2202** can be coated with an adhesive. The central portion **2206** of the adhesive pad **2202** can also have an adhesive coating the top surface. The central portion **2206** can be sized and shaped to match a catheter hub **2208** or other device such that the catheter hub can be adhered to the central portion **2206**. The side portions **2204** can be optionally torn away from the central portion **2206**. The boundary line between the side portions **2204** and the central portion **2206** can be perforated or scored to facilitate separation of the side portions **2204**.

FIG. **23** illustrates another embodiment of a securement device **2300** having an adhesive pad **2302** and a nested hub **2304** secured to the adhesive pad **2302**. The nested hub **2304** can have a receiving portion **2306** shaped to receive a catheter hub. The receiving portion **2306** can also have suture tab receiving portions **2308** for receiving the suture tabs on the catheter hub. The suture tab receiving portion **2308** can have a post **2310** for securing the suture tabs. The nested hub **2304** can have a strap **2312** attached to one side of the nested hub **2304** and a buckle slot **2314** located on the other side of the nested hub **2304**. The strap **2312** can be used to secure a catheter hub placed in the nested hub **2304**. To secure the catheter hub, the strap **2313** can be passed through the buckle slot **2314**, tightened, and then fastened to itself using a fastener such as hook and loop fasteners.

FIGS. **24**A and **24**B illustrate another embodiment of a securement device **2400**. The securement device **2400** is formed from an adhesive pad **2402** that has an embedded hook **2404** that can pass through the hole in the suture tab and lock the suture tab in place. The hook **2404** can be made of a metal or plastic wire. The hook **2404** can be rotationally or pivotably attached to the adhesive pad **2402** and can be biased to a closed position. The hook **2404** can have an axle portion **2406** that can be rotatably attached to the adhesive pad **2402**. For example, the axle portion **2406** can be threaded through the adhesive pad **2402** or can be disposed in a channel in the adhesive pad **2402**. The channel can be formed by molding or by folding a portion of the adhesive pad over itself. The bias can be applied by a spring attached to the hook **2404**. To pass the hook **2404** through the suture tab, the hook **2404** can be

rotated so that it faces upwards and can be threaded through the hole in the suture tab. When the hook **2404** is released, the hook's **2404** natural bias to the closed position can automatically rotate the hook **2404** back to the closed position, thereby securing the suture tab. For securing a catheter hub having two suture tabs, two securement devices **2400** can be used as shown in FIG. **24**B to secure the catheter hub to the patient.

FIG. **25** illustrates another embodiment of a securement device **2500**. The securement device **2500** includes a vacuum formed blister pack **2502** that can be formed to match the size and shape of any catheter hub or other portion of a catheter or medical device by using the catheter hub, catheter or medical device as a mold for the blister pack. The blister pack **2502** can have a base **2504** with an adhesive that allows the base **2504** to function as an adhesive pad. The base **2504** can be adhered directly to the patient's skin or adhered to an adhesive pad or overlay **2506** with an integrated tube or line management structure **2508**. In some embodiments, the blister pack **2502** can be integrated into the adhesive pad with the line management structure.

FIGS. **26**A-**26**D illustrate another embodiment of a securement device **2600**. The securement device **2600** is formed from a coiled wire with a plurality of spiral loops **2602** and a penetrating tip **2604**. The securement device **2600** can also have a handle **2606** to facilitate rotation of the securement device **2600** over the catheter. The securement device **2600** is placed over a catheter such that the catheter is disposed through the loops **2602** of the wire. Rotating the coils drives the penetrating tip **2604** in a corkscrewing action into the patient's skin, thereby securing the catheter to the patient's skin. The catheter can have grooves for guiding and holding the loops of the wire coil in place on the catheter. The coils can grip the catheter sufficiently to secure the catheter on the patient. In some embodiments, the diameter of the loops in an unstressed state is smaller than the diameter of the catheter in order for the loops to provide sufficient force against the catheter.

FIGS. **27**A-**27**E illustrate another embodiment of a securement device **2700**. The securement device **2700** is a catheter anchor formed by an anchor portion **2702** having one or more hooks **2704** extending from a collar portion **2706**. For example, the anchor portion **2702** can have two hooks, three hooks, four hooks, or greater than four hooks. The collar portion **2706** fits over the catheter and can be secured or fastened to the catheter. In some embodiments, the collar portion **2706** can be snapped over the catheter. An anchor sheath **2708** can be disposed over the anchor portion **2702** to cover the hooks **2704** during catheter insertion. The hooks **2704** can be elastic or superelastic such that the hooks can be straightened out by the sheath in a covered low profile configuration. To deploy the hooks **2704**, the sheath **2708** can be retracted from the anchor portion **2702** to expose the hooks **2704**, which bend elastically back towards its deployed configuration with the tips of the hooks extending outwards and into the tissue, thereby anchoring the catheter. In some embodiments, the catheter securement device **2700** can be advanced over the catheter and partially into the patient's skin before the sheath **2708** is retracted to expose the hooks **2704**. The remove the catheter, the sheath **2708** can be advanced back over the hooks **2704** to compress the hooks against the catheter, thereby allowing the catheter to be removed.

FIGS. **28**A-**28**E illustrate another embodiment of a securement device **2800**. The securement device **2800** can be made from a snap on sheath **2802** or tube that can snap onto a catheter to provide anchoring. The sheath **2802** can have a slit **2804** or gap that allows the sheath **2802** to be snapped onto the catheter. The securement device **2800** can have a radially expandable anchor portion **2806** that has a deployed configuration and a non-deployed configuration, where the anchor portion **2806** has a low profile in the non-deployed configuration, as shown in FIG. **28**B, such as being in line with the rest of the sheath **2802**. In the deployed configuration, the anchor portion **2806** can have a radially expanded profile with an increased diameter relative to the non-deployed configuration, as illustrated in FIG. **28**C. In some embodiments, the anchor portion **2806** can be deployed by actuating the proximal portion **2808** of the sheath **2802**, for example by retracting the proximal portion **2808**, which retracts the distal portion **2810** of the sheath **2802** and compresses the anchor portion **2806**. As the anchor portion **2806** is axially compressed, it expands radially outwards, thereby anchoring the catheter in the tissue. In some embodiments, the anchor portion **2806** can be deployed within the epidermis or dermis layer of the skin, or between the epidermis and dermis, or below the epidermis or dermis, such as subcutaneous deployment for example. In some embodiments, the anchor portion **2806** can be deployed within other tissues or cavities or lumens within the body. In some embodiments, the anchor portions **2806** can be stowed after deployment by, for example, advancing the proximal portion **2808** to advance the distal portion **2810** of the sheath **2802** and decompress the anchor portion **2806**. As the anchor portion **2806** is axially decompressed, it retracts radially inwards until it no longer protrudes from the catheter or is flush with the catheter.

In some embodiments, as illustrated in FIG. **28**D, the proximal portion **2808** can be provided with grip wing **2812** or other gripping features that facilitate the gripping, actuating, retracting and/or advancing of the proximal portion **2808** to deploy or stow the anchor portion **2806**. In some embodiments, as illustrated in FIG. **28**E, the sheath **2802** can have a inflation port **2814** that is in fluid communication of the anchor portion **2806** and that allows the anchor portion **2806** to be inflated and deflated to radially expand and retract the anchor portion **2806**. The anchor portion **2806** can be inflatable such as a balloon, for example.

FIGS. **29**A and **29**B illustrate another embodiment of a securement device **2900** with an expanding anchor portion **2906** that is similar to the expanding anchor portion described above in FIGS. **28**A-C. In some embodiments as illustrated in FIGS. **29**A and **29**B, the securement device **2900** can have a sheath **2902** that completely encircles the catheter **2902** and can be integrated with the catheter. In some embodiments, the sheath **2902** can have a longitudinal slit as described above to allow the securement device **2900** to be removably attached to the catheter. The sheath **2902** can have a radially expandable anchor portion **2906** that can be made of a mesh or woven material. In other embodiments, the anchor portion **2906** can be made of a membrane or sheet. As described above, the proximal portion **2908** of the sheath **2902** can be actuated, for example retracted proximally, which causes the distal portion **2910** of the sheath **2902** to also retract proximally to collapse and radially expand the anchor portion **2906**. Also as described above, the proximal portion **2908** can be advanced distally to decompress the anchor portion **2906** to restore the anchor portion **2906** to its non-deployed state. The proximal portion **2908** can have a gripping portion **2912** that extends radially outwards and facilitates the gripping, actuating, retracting and/or advancing of the proximal portion **2908** to deploy or stow the anchor portion **2906**.

FIGS. **30**A and **30**B illustrate another embodiment of the securement device **3000** with two expandable anchor portions, a distal expandable anchor portion **3006** and a proximal expandable anchor portion **3007**. The two anchor portions can be disposed on a sheath **3002** as described above and can

be actuated in a similar manner to deploy the anchor portions. Providing a second anchor portion allows the anchor portions to sandwich the skin or other tissue layer between the anchors, thereby reducing the in and out movement of the catheter in the tissue. For example, the distal anchor portion **3006** can be deployed subcutaneously and the proximal anchor portion can be deployed **3007** against the outside surface of the skin. In some embodiments, the two anchors can be simultaneously deployed by a single actuation of the sheath, while in other embodiments, the two anchors can be independently deployed.

FIGS. **31**A-**31**C illustrate another embodiment of a securement device **3100** that can be reversibly attached to a catheter. The securement device **3100** can have a base **3102** and a cover **3104**. The base **3102** and cover **3104** can be attached together via a hinge **3105** or other mechanism that allows the cover **3104** to pivot with respect to the base **3102**. The base **3102** and the cover **3104** can have a channel **3106** that is configured to receive the catheter and in conjunction with the base and cover forms a catheter shaft clamp area. The channel **3106** can have an opening in the proximal end of the base and cover assembly and an opening in the bottom portion of the base **3102** that allows the catheter to pass through the base and cover assembly and into the patient's skin. The cover **3104** can have one or more, for example two, anchor tangs **3108** that can be elongate and arcuate and have tissue penetrating tips. The base **3102** can have penetration guide channels **3110** that receive the anchor tangs **3108** and help guide and angle the anchor tangs **3108** into the skin. In some embodiments, the anchor tangs **3108** are configured to achieve subdermal or subcutaneous penetration. In some embodiments, the anchor tangs extend from the bottom surface of the cover **3104** such that cover is in the fully opened configuration, the tissue penetrating tips of the anchor tangs are disposed within the penetration guide channels **3110**. The anchor tangs **3108** can be deployed to penetrate the patient's skin by closing the cover **3104** which drives the anchor tangs **3108** into the patient's skin. The anchor tangs **3108** can be driven into the skin at an angle such that the tissue penetrating tips are directed proximally. The guide channels **3110** can be oriented to slant proximally to facilitate entry of the anchor tangs **3108**. When fully deployed, the anchor tangs **3108** can be positioned substantially longitudinally within or under the skin relative to the skin layer. In addition, the guide channels **3110** are located around or proximate the opening on the base **3102** where the catheter enters the skin. The location and orientation of the guide channels **3110** along with the shape and orientation of the anchor tangs **3108** allow the anchor tangs to enter the skin at the same location as the catheter entry so that no new entry site is created. Instead, the anchor tangs **3108** can enter alongside the catheter shaft. The cover **3104** can be secured to the base using a latching mechanism **3112** or other locking or fastening mechanism.

FIGS. **32**A-**32**P illustrate another embodiment of a securement device **3200**. The securement device **3200** can be modular such that the securement device **3200** can be independently attached to each suture tab on a catheter hub. The structure and use of the securement device **3200** is similar in some respects to the embodiments described above with respect to FIGS. **1**-**3**, for example. As shown in FIGS. **32**A and **32**B, the securement device **3200** can include independent and modular engagement tabs **3202** that are configured to engage the suture tabs and thereby secure the catheter hub to the patient's skin. For a typical catheter with two suture tabs, the securement device **3200** includes two engagement tabs **3202**. In general, the securement device **3200** has an equal number of engagement tabs **3202** as there are suture tabs. Since the engagement tabs **3202** are independent and modular, more or fewer engagement tabs **3202** can be used as needed.

The engagement tab **3202** can have a base **3204** that is attached to an adhesive pad **3206**. The base can have a post **3208** sized and shaped for engaging and passing through the hole in the suture tab. The post **3208** can extend upwards from the base **3204**. In some embodiments, the post **3208** can be biased away from the side of the base **3204** that faces the catheter hub, such that the distal end of the post **3208** is biased away from the suture tab when the base **3204** and post **3208** are engaged with the suture tab. The biased post **3208** aids in preventing or reducing the likelihood of accidental disengagement of the engagement tab **3202** from the suture tab when the catheter or catheter hub is pulled upwards away from the patient's skin. As the catheter or catheter hub is pulled upwards, the biased post **3208** can exert an outwards and/or downwards force on the suture tab that provides resistance to further upwards movement of the catheter or catheter hub, thereby preventing and/or resisting accidental disengagement of the engagement tab **3202** from the suture tab. In some embodiments, the post **3208** can be angled between about 0 to 30 degrees, 0 to 25 degrees, 0 to 20 degrees, or 0 to 15 degrees from the vertical axis. In some embodiments, the post **3208** is angled at least about 1, 2, 3, 4, 5, 10, 15, 20, 25, or 30 degrees from the vertical axis. In some embodiments, the post **3208** can be angled less than about 5, 10, 15, 20, 25, or 30 degrees from the vertical axis. About or approximately as used herein can mean within 10%, 20%, or 30%, for example. In some embodiments, the post **3208** can be tapered such that the distal end of the post **3208** has a smaller diameter than the proximal portion of the post **3208**. In some embodiments, the post **3208** is not tapered and has a constant diameter. In some embodiments, the distal end of the post **3208** can include a barb, ball, or other retaining mechanism to improve retention of the post within the hole of the suture tab.

The engagement tab **3202** can further include a slidable cover **3210** that fits over and covers the base **3202** and the post **3208**. The cover **3210** can be retracted away from the catheter hub to expose the post **3208** in an open configuration and can be advanced towards the catheter hub to cover the post **3208** in a closed configuration. The cover **3210** can be slidably mounted to the base **3202** by using, for example, a groove and rail connection between the two. For example, the cover **3210** can have two rails **3212** that fit into corresponding grooves **3214** located on the base **3202** and allow the cover to slide back and forth over the base **3202**. The cover **3210** can have grip portions **3218** that protrude outwards from the cover **3210** in a direction transverse to the sliding motion of the cover **3210**. The grip portions **3218** facilitate gripping and manipulation of the cover **3210** by the operator.

In some embodiments, the engagement tab **3202** can be made of a flexible or semi-rigid material that can bend or flex in response to applied stress. The added flexibility enables the engagement tab **3202** to absorb force exerted on the engagement tab **3202**, thereby reducing the force exerted on the catheter and/or catheter hub which reduces the risk of accidental dislodgement of the catheter from the patient.

As illustrated in FIGS. **32**C and **32**D, the adhesive pad **3206** can include a peelable backing layer **3216** to cover the adhesive on the adhesive pad **3206**. The backing layer **3216** can have a pull tab for removing the backing layer from the adhesive pad **3206** and thereby exposing the adhesive on the adhesive pad **3206**. In some embodiments, the backing layer **3216** can be divided into multiple pieces, each with a separate tab to facilitate peeling. For example, the backing layer **3216** can have a first portion that covers the area around the base

3202 and a second portion away from base 3202. Having two portions allows only a relatively small portion of the adhesive to be exposed while positioning the securement device 3200 on the patient, which may allow easier repositioning of the securement device. In other embodiments, the backing layer 3216 can be formed of a single piece with a single tab to facilitate peeling. The backing layer 3216 can be removed before the adhesive pad 3206 is pressed into contact with the patient's skin. In some embodiments, the backing layer 3216 can be removed prior to inserting the post through the hole in the suture tab. In other embodiments, the backing layer 3216 can be removed after inserting the post through the hole in the suture tab.

In some embodiments, the adhesive pads 3206 can use a combination of an acrylic adhesive for the high stress points and a hydrocolloid adhesive for long term securement and comfort. In some embodiments, the adhesive pads 3206 can use either the acrylic adhesive or the hydrocolloid adhesive. The backing layer 3216 can be made from paper, plastic or any other suitable material that can be peeled from the adhesive. In some embodiments, a two or more securement devices 3200 can be disposed on a single backing layer 3216 that can be perforated or scored between the adhesive pads 3206 of the securement devices 3200 to allow the securement devices 3200 to be held together during packaging and easy separation of the securement devices 3200 from each other before use. The adhesive pad substrate can be a skin tone fabric or a clear material that allows for the skin color to show through in order to minimize the visual impact of the device on the patient who may have to endure the catheter for many days. The adhesive pad 3206 can be made of a flexible material so that it can conform to that geometry of the patient's body.

FIGS. 32E-32G illustrate an embodiment of the engagement tab 3202 with the backing layer removed. In addition, FIG. 32E illustrates a cross-sectional view of the engagement tab 3202 along a plane that passes through the groove 3214 and rail 3212 connection. The slidable groove and rail connection can be provided with a locking feature, such as a snap-lock feature that secures the cover 3210 over the base 3204 in the closed configuration. The snap-lock feature can be made by, for example, providing a rounded protrusion 3220 in the groove 3214 or slot and a matching or complementary rounded indentation 3222 in the rail 3212. Alternatively, the rounded protrusion 3220 can be placed on the rail 3212 and the rounded indentation 3222 can be placed on the groove 3214. In the closed configuration, the rounded protrusion 3220 is placed within the rounded indentation 3222, thereby securing the cover 3210 in place over the base 3204. The cover 3210 can be made of a flexible material such that upon the application of force, the rails 3212 can be displaced outwards to free the rails from the locked position. To return the cover 3210 back to the locked position, force can be applied to slide the rails within the slot or groove until the rounded protrusion 3220 snaps back into the rounded indentation 3222. In some embodiments, the locking feature provides a tactile and/or audible click to alert the operator that cover 3210 has been moved to the locked or unlocked configuration. In addition, the base 3204 can be made of a different color that the cover such that the operator is provided with a visual indicator of the open or close configuration of the cover 3210.

FIGS. 32H-32O illustrate various views of the cover 3210 and the base 3204. In addition to the features described above, FIGS. 32I and 32M, illustrate a stop feature that prevents the cover 3210 from sliding off the base 3204. The stop feature can also be integrated into the groove and rail connection by, for example, providing a transversely extending rail stop 3224 and a corresponding transversely extending groove stop 3226 that are designed to abut against one another to stop further movement of the cover 3210 relative to the base 3204 when the cover 3210 is at the fully opened configuration.

Because the securement device 3200 comes in modular parts, the securement device can accommodate catheter hubs of any width that uses suture tabs. This enables a universal fit for many catheter styles or brands. As described above, a modular securement device 3200 provides many benefits.

Attaching the engagement tab 3202 to the suture tab on the catheter is a simple maneuver that can be accomplished by simply engaging the post 3208 of the engagement tab 3202 with the hole of the suture tab from the bottom up, as illustrated in FIG. 32P. The post 3208 can be exposed, if covered, by retracting the cover 3210 away from the catheter as described above. This requires very little manipulation of the indwelling catheter which is a priority of users. Since the modular engagement tabs 3202 are independent, each engagement tab 3202 can be optimally positioned sequentially according to the patient anatomy. This lends flexibility of placement which is another important feature for users. In addition, in some embodiments, the fit of the post 3208 within the hole of the suture tab can leave some room for the post 3208 to pivot within the hole, which can further enhance the ability of the modular securement system to conform to the variable geometry of the patient's body. This can be accomplished, for example, by making the post 3208 have a smaller diameter than the hole of the suture tab. The ability of the engagement tabs 3202 to pivot on the suture tab allows the engagement tabs 3202 and catheter hub or other device to each lie within different planes if needed, which aids the system in conforming to the patient's body. The adhesive pads 3206 of each engagement tab 3202 can be trimmed to any shape if needed. Once both engagement tabs 3202 are in place, the catheter is held extremely well by the adhesive pads 3206. The shape and placement of adhesive provides resistance to lateral and upwards pulling of the catheter or tubing, thereby ensuring proper securement of the catheter to the patient. In addition, after the post 3208 of the engagement tab 3202 has been inserted through the suture tab, the cover 3210 can be slid back over the base 3204 and post 3208 to secure the suture tab within the engagement tab 3202. The sliding action to lock the cover 3210 in place avoids downwards pressure to close the device which can reduce unwanted motion being transmitted to the indwelling catheter.

In some embodiments, the engagement tab 3202, and particularly the cover 3210, can be dome shaped with curved surfaces. The dome can have a continuously smooth surface or a non continuous smooth surface with a flattened top portion. In some embodiments, a dome with a continuously smooth surface can be more easily covered with an overdressing such that pockets of air trapped between the overdressing and dome are reduced. The engagement tab 3202 can be made of a transparent material, such as a transparent plastic, that allows the user to visualize the post 3208 through the cover 3210. The post 3208 can be made opaque so that it is easier to visualize. For example, the post can be coated or made from an opaque material. The discrete shape and size of the dome permits full visualization of the catheter hub and skin entry point. The engagement tab 3202 can have a low profile which enables smooth placement of overdressings, such as Tegaderm™, over the catheter, catheter hub, and/or securement devices 3200. For example, the engagement tab 3202 can have a height that is less than or equal to the height of the catheter and/or the catheter hub. This results in a securement device 3200 with optional overdressing that is no higher than

the catheter or catheter hub itself with no obtrusive bumps, housings, catch points and the like for maximum patient comfort while reducing the likelihood of accidentally snagging and dislodging or removing the catheter, catheter hub and/or securement device **3200**.

As described above in the other embodiments, the securement device **3200** can be used to secure a variety of different catheters and be used with a variety of different adaptors and line management devices.

The foregoing descriptions of specific embodiments of the present invention have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the invention to the precise forms disclosed, and obviously many modifications and variations are possible in light of the above teaching. For example, features described in one embodiment can be used in another embodiment. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, to thereby enable others skilled in the art to best utilize the invention and various embodiments with various modifications as are suited to the particular use contemplated.

What is claimed is:

1. A securement device for securing a medical device having a suture tab to a patient's body, the device comprising:

an adhesive pad having a first surface coated with an adhesive and a second surface;

a base disposed on the second surface; an upwardly extending post that extends from the base and away from the adhesive pad, wherein the post is configured to engage the suture tab; and

a cover that is slidably attached to the base portion and configured to have a closed configuration that covers the post and an open configuration that exposes the post.

2. The device of claim **1**, wherein the cover is reversibly secured to the slot by a locking mechanism.

3. The device of claim **2**, wherein the base has a slot and the cover has a rail which is slidably disposed in the slot.

4. The device of claim **3**, wherein the locking mechanism generates a tactile indicator when the cover is moved between the closed configuration and open configuration.

5. The device of claim **3**, wherein the locking mechanism generates an audible indicator when the cover is moved between the closed configuration and open configuration.

6. The device of claim **3**, wherein the locking mechanism comprises a rounded protrusion disposed within the slot and a complementary rounded indentation disposed on the rail.

7. The device of claim **3**, wherein the locking mechanism comprises a rounded protrusion disposed on the rail and a complementary rounded indentation disposed within the slot.

8. The device of claim **1**, further comprising a backing layer disposed over the adhesive, wherein the backing layer comprises a pull tab.

9. The device of claim **8**, wherein the backing layer comprises a first portion disposed proximate the base and having a first pull tab, and a second portion disposed away from the base and having a second pull tab, wherein the first portion and the second portion are separably removable.

10. A system for securing a medical device to a patient's body, the system comprising:

an adaptor having a first suture tab, wherein the adaptor is removably disposed over a portion of the medical device; and

a first securement device comprising an adhesive pad having a first surface coated with an adhesive and a second surface, a base disposed on the second surface, an upwardly extending post that extends from the base and away from the adhesive pad, and a cover that is slidably attached to the base portion and configured to have a dosed configuration that covers the post and an open configuration that exposes the post, wherein, the post is disposed through the first suture tab.

11. The system of claim **10** further comprising an overdressing covering at least a portion of the first securement device, adaptor and the medical device.

12. The system of claim **10**, further comprising a second securement device that is secured to a second suture tab on the adaptor, wherein the second securement device is secured independently of the first securement device.

13. The system of claim **10**, wherein the adaptor comprises a channel for receiving the portion of the medical device.

14. The system of claim **10**, wherein the channel comprises a deformable liner.

15. The system of claim **10**, wherein the deformable liner is elastic and reversibly deformable.

16. The system of claim **10**, wherein the deformable liner is made of foam.

17. A method of securing a medical device having is first suture tab to a patient's body, the method comprising:

providing a first securement device comprising an adhesive pfd having a first surface coated with an adhesive and a second surface, a base disposed on the second surface, an upwardly extending post that extends from the base and away from the adhesive pad, and a cover that is slidably attached to the base portion and configured to have a closed configuration that covers the post and an open configuration that exposes the post;

disposing the post through the first suture tab;

sliding the cover to the closed configuration; and

adhering the adhesive pad to the patient's body.

18. The method of claim **17**, further comprising disposing an overdressing over at least a portion of the first securement device and medical device.

19. The method of claim **17**, further comprising providing a second securement device and securing the second securement device to a second suture tab on the medical device, wherein the second securement device is secured independently of the first securement device.

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